AIRBORNE CONCENTRATIONS OF FORMALDEHYDE IN A PATHOLOGY UNIT

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A research report submitted to the faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfillment of the requirements for the degree of Masters of Public Health (Occupational Hygiene)

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Declaration

I, Hlosi Ntsuba declare that this research reportòAirborne concentration of Formaldehyde in a Pathology Unitò is my own work. It is being submitted for the degree of Master of Public Health (Occupational Hygiene) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

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H.S. Ntsuba

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Airborne Concentrations of Formaldehyde in a pathology unit

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Abstract

Background

This descriptive cross-sectional study aimed to assess the exposure to formaldehyde associated with the tasks in a pathology laboratory unit. The study objectives were to describe the tasks involving the use of formaldehyde in the unit and assess exposure to formaldehyde as well as assess the effectiveness of existing engineering/ventilation system control methods.

Methods

The study involved observation and description of all tasks carried out in the laboratory, assessing exposure to formaldehyde and physical measurements of laboratory parameters such as area and volume. Exposure assessment involved three levels: task-based exposure assessment; personal exposure assessment and area exposure assessment. Formaldehyde measurements, by means of shadow sampling (personal breathing zone sampling by another person shadowing person being sampled) were taken using the formaldehyde meter. Data were summarised using means, medians and proportions and results were presented in figures and tables. For significance testing, an analysis of variance was carried out on the log-transformed data and p-value less than 0.05 were interpreted as statistically significant.

Results

Not all tasks in the laboratory were done according to the standard operating procedures. In general, exposure to formaldehyde was highest among the assistants group who were mostly responsible for high-exposure tasks. Mean STEL values for assistants, technologists and pathologist were 2.37ppm, 1.21ppm and 1.59ppm respectively, while for TWA, the figures were 0.60ppm, 0.36ppm and 0.21ppm. For short term exposures (STEL and peak values) pathologist exposure levels were higher than those of technologists while technologists were higher for long term exposures (daily exposure and 8-hour TWA). Daily exposure varied significantly for assistants and technologists but not for pathologist. Despite the use of engineering exposure controls for formaldehyde, 27/28 of all tasks were higher than the ACGIH threshold ceiling limit of 0.3ppm, 0.008ppm MRL value and 0.002ppm REL-TWA value.

Conclusion

The results have shown exposures among the employees of all job categories in this study, with laboratory assistants being the most exposed. Currently installed local ventilation system requires to be upgraded in accordance with best practices of 3.5m/s for air speed. Training, on PPE usage together with the medical surveillance should also be implemented.

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Nomenclature

ACGIH
American Conference of Governmental Industrial Hygienists

ALS
Amyotrophic Lateral Sclerosis Disease

ATSDR
Agency for Toxic Substances and Disease

BDL
Below Detection Limit

CA
Chromosomal Aberrations

Cal/EPA
California Environmental Protection Agency

CL
Control Limit

OEL
Occupational Exposure Limit

DNA
Deoxyribonucleic Acid

H_2CO
Chemical Formula for Formaldehyde

IARC
International Association of Research in Cancer

IDLH
Immediately Dangerous to Life or Health Concentration Value

LCD
Liquid Crystal Display

MAPK
Mutagen Activated Protein Kinase

MRL
Minimum Risk Level

NFDA
National Funeral Directors Association of America

NIOH

National Institute of Occupational Health

NIOSH
National Institute of Occupational Safety and Health in the USA

NOAEL
No observed adverse effect level

OSHA PEL
Occupational Safety and Health Administration Permissible Exposure Limit

PPB
Parts per billion

PPE
Personal Protective Equipment

PPM
Part Per Million

RL
Recommended Limit

REL
Reference Exposure Level

SA
South African (Republic)

SOP
Standard Operating Procedure

STEL
Short term Exposure Limit

TB
Tuberculosis

TLV
Threshold Limit Value

TWA
Time-Weighted Average

USA
United States of America

STDev
Standard Deviation

WHO
World Health Organisation

Definitions

Activity - A sequence of actions treated as a basic unit of task.

Aldehyde - Any of a class of highly reactive organic chemical compounds obtained by oxidation of primary alcohols, characterized by the common group CHO.

Approved Inspection Authority(AIA) ï An inspection authority approved by the chief inspector: Provided that an inspection authority approved by the chief inspector with regard to any particular service shall be an Approved Inspection Authority with respect to that service only.

Common name - In science, a common name is any name by which a species is known that is not the official scientific name.

DNA ï Molecular basis of heredity in many organisms, and are constructed of a double helix held together by hydrogen bonds between purine and pyrimidine bases which project inward from two chains containing alternate links of deoxyribose and phosphate.

Electrophilic aromatic substitution - Is an organic reaction in which an atom, usually

Electrophile - A chemical compound or group that is attracted to electrons and tends to accept electrons.

Electrophilic addition - Is an addition reaction where, in a chemical compound, a pi-bond is removed by the creation of two new covalent bonds. In electrophilic addition reactions, common substrates have a carbon-carbon double bond or triple bond. General representation: Y-Z + C=C Ÿ Y-C-C-Z.

Face Velocity- Is the average of series of measurements taken in various positions across the face of the booth or ventilation hood.

Job - The task(s) done by one person daily during any 8 hour period while at work.

Job Type/Category/Group ï This refers job done by assistants, technologist and Pathologists.

Minimum Risk Levels (MRL) ï is an estimate of daily human exposure to hazardous Substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specified duration of exposure (15 minutes or 8 hours). They are generally based on the most sensitive chemical ï induced end point considered to be of relevance to humans.

No Observed Adverse Effect Level (NOAEL) ï It denotes level of exposure of an organism by experiment or observation, at which there is no biological or statistically significant increase in the frequency or severity of any adverse effects in the exposed population when compared to its appropriate control.

Occupational exposure limit (OEL) – They are numerical values, which indicate whether an exposure may cause harm. Can not be measured or determined and are laid down in legislation.

Oxidation - Any chemical reaction in which a material gives up electrons when the material combines with oxygen.

Process - A goal-directed, interrelated series of tasks.

Saturated solution - A solution that contains all of a substance capable of dissolving; a solution of a substance in equilibrium with an excess dissolved substance.

Tissue fixation -The technique of using chemicals that prevent tissue decay in the preparation of cytologic, histologic, or pathologic specimens for the purpose of maintaining the existing form and structure of all the constituent elements for later examination through microscope.

Systemic name - A name composed of words or symbols that precisely describe chemical structure, thus allowing the structure of a chemical to be derived from its name hydrogen, appended to an aromatic system is replaced by an electrophile.

Task - A goal-directed, interrelated series of activities. There are 28 tasks for this project as outlines in the methods section. These tasks will be described in details in the study.

Shadow sampling – Done through another person holding sampling media in the breathing zone of the person being sampled. The person being sampled does not wear the instrument but the sampling person follows the person as he/she does her/his activities or task for the duration of the activities/task(s).

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CHAPTER 1

1. Literature review and introduction

1.1 Characteristics of formaldehyde

Formaldehyde is a flammable substance with a strong smell.[1,2] It is a gas at room temperature and unstable in this form.[1,2,3,4] It is the simplest aldehyde chemical compound with a chemical formula of H_2CO and is a colourless, flammable gas with a strong suffocating smell.[2] It is an organic compound containing a terminal carbonyl group consisting of exactly one carbonyl. Formaldehyde exists in several forms aside from H_2CO. The cyclic trimer trioxane and the polymer paraformaldehyde exist in solid form and are sold and marketed as a trioxane. Paraformaldehyde is a polymer with 8-100 units of formaldehyde.[4] The systemic name for formaldehyde is methanal. Other common names include formalin, formol, methyl aldehyde, and methyl oxide. At room temperature formaldehyde is readily soluble in water.[2,4]

Formaldehyde is normally diluted with water and a small amount of methanol is added to make it more stable and reduce the intrinsic polymerization at room temperature. It is soluble in water, acetone, benzene, chloroform diethyl ether and ethanol.[4] Solutions of formaldehyde are commonly known as formalin. Typical commercially available formalin contains about 37% of formaldehyde by weight (40% by volume), in water with 6-13% methanol.[2]

The formaldehyde is also a natural byproduct of many living organism and is found in the environment. It is released during biomass, forest and bush fires.[5] In water, it is formed by the irradiation of humid substances by sunlight.[6] As the most common aldehyde in the environment, it has the natural background concentration of < 1mg/m^3 with the mean of about 0.5mg/m.[3,7] It has been found that the levels of formaldehyde in outdoor air are generally below 0.001mg/m^3 in remote areas and below 0.02 mg/m^3 in urban settings. The level of formadehyde in indoor air of houses was found to be around 0.02 ï 0.06 mg/m^3. Mobile homes' had higher results of up to 0.5 mg/m^3 due to the material that was used to build them.[8]

1.2 Uses of formaldehyde

Formaldehyde is a chemical of metabolic, medical, industrial and societal importance.[1] Its important biological use is to preserve, and deter the spoilage of human tissue caused by microbial contamination.[4] In the pathology units, formalin is used to preserve body parts of cardio-respiratory organs (lungs and hearts) for *post mortems* diagnosis. Formaldehyde preserves or fixes tissue or cells by irreversibly cross-linking primary amine in proteins with other nearby nitrogen atoms in the protein or DNA through a CH_2 linkage.[4]

Formaldehyde is also a product of many industrial processes. The processes use catalytic and vapour-phase oxidation of methanol to produce formaldehyde. In the United States of America (USA), formaldehyde produced is used in the production and manufacturing of phenolic acid (19%), urea-formaldehyde resins (19%) and urea-formaldehyde concentrate, used mostly in the manufacture of particle board, fibreboards paper treating, textile treating and surface coating. Urea and melamine resins (8%) are used extensively in the production of adhesives and binders in wood products, pulp and paper production, textile and finishing industries. Methylene diisocyanate (6%) and acetylenic chemicals are used in the drugs, animal feeds, plasticizers and perfumes. Formaldehyde is also used to make polyacetal resins (11%), for production of plastics. Formaldehyde is very important as the intermediate in the manufacturing of many industrial chemicals. These chemicals include the production of pentaerythritol (5%) and hexamethylenetetramine (4%) used to make explosives. Other miscellaneous products account for 12% formaldehyde production. These include nitroparraffin derivatives, chelating agents, pyridine chemicals, trimethylolethane. [9,10]

1.3 Production

Most literature statistics on the production of formaldehyde are from USA. According to the USA statistics, production of 37% aqueous formalin production was 5.14 million metric tones (11.3 billion lb) per annum in 1998. The annual growth rate between 1997 and 1998 was 2.7%. This compared to the production of 848,000 metric tones (1,87 billion lb) in 1960. The formaldehyde is thought to have been commercially produced from 1900s and rank among the top 25 of 50 highest volume chemicals produced in the USA. [9,10,11]

1.4 Exposure

Formaldehyde is produced into the atmosphere by both natural and anthropogenic sources. The two most common methods of human exposure are by inhalation and dermal contact. Ingestion has minimum exposure in relation to the two most common methods.[10,11]
Deliberate exposure through excessive ingestion of formaldehyde is a method of exposure misused to commit suicide and homicide by people.

Potential occupational exposure to formaldehyde may occur during the production or use of end products containing formalin in the industries (table 1).[12]

Table 1: Typical exposures to formaldehyde by industry as per NIOSH survey reports

Industry	**Formaldehyde Level**
Fertilizer Production	0.2 - 1.9 ppm
Dyestuffs	<0.1 - 5.8 ppm
Textile Manufacture	<0.1 - 1.4 ppm
Resins (Foundry)	<0.1 - 5.5 ppm
Bronze Foundry	0.12 - 0.8 ppm
Iron Foundry	<0.02 - 18.3 ppm
Treated Paper	0.14 - 0.99 ppm
Hospital Autopsy Room	2.2 - 7.9 ppm
Plywood Industry	1.0 - 2.5 ppm

Source: DHHS (NIOSH) publication No. 81-111

The exposure levels by NIOSH table 1 above indicate different typical levels of exposure by industry. The high levels of exposure being the people working in the hospital autopsy room.[12] This is similar to job performed by most pathology laboratory workers.

Formaldehyde can be formed in the troposphere by the photochemical oxidation of many natural organic compounds such as methane, isoprene and other organic compounds such as pollutants from mobile and stationery sources, alkanes, alkenes, aldehydes and alcohols.[13] The photochemical oxidation in urban areas due to pollution episodes may contribute 70-90% of formaldehyde formed from abundant and diverse formaldehyde precursors.[14,15,16] The photochemical formation of formaldehyde was found to be more important than direct emission of formaldehyde in contributing to high levels of atmospheric concentration of formaldehyde in studies conducted in USA and Japan.[17,18,19]

There has been reported exposure to formaldehyde in construction, agriculture, forestry and service industries. Exposure concentrations are highly variable between workplaces. The table 1 above also shows this exposure variability within the same industry. The reported mean concentrations in the air of factories producing formaldehyde-based resins was found to vary from <1ppm to over 10ppm and specialised workers in construction industry such as wooden floor varnishing workers are reported to be exposed to formaldehyde levels of 2-5ppm during the application of each varnish coat. The estimated number of varnish coats by each worker is 5-10 coats.[20]

In forestry industries, exposure due to formaldehyde from exhaust has been noted in studies done in Sweden and Finland but was found to be less than 0.1ppm. The agricultural sector has high exposure to formaldehyde. The levels are between 7-8 ppm during the application as both preservative for fodder and disinfectant for brooding houses.[20] Many fruits and some food contain formalin.[21] When fruits are ingested by mammals (including humans), its xenobiotics are oxidatively metabolised producing formalin as a by-product.[9,10,11] As an intermediate metabolic product, it is present in most living organisms. It is also produced and emitted by different bacteria, algae, plankton and vegetation.[4]

1.5 Health effects of formaldehyde

According to Malaka and Kodama, the ubiquitous nature of formaldehyde demands that its health effects be properly understood.[1]This is even more important where people are continually exposed in occupational settings.

Formaldehyde can cause acute health effects ranging from irritation of the eyes and respiratory tract to headache, throat burning sensation and sensitisation of the skin.[3] In the body, formaldehyde converts to formic acid giving rise to blood acidity, which may result in blurred vision or complete blindness, hypothermia, and even coma or death.[3, 4]

There are a number of research papers that reported observed histopathological effects such as hyperplasia, squamous metaplasia, inflammation, erosion and ulceration and sustained proliferation response in the rats nasal cavity at concentrations of 3.1ppm and above.[22-25]

In the study of carcinogecity of formaldehyde in both the mice and rats conducted by Keasns et al, both groups of 120 male and 120 female rats and mice were exposed to concentration of formaldehyde at 0, 2.0, 5.6 and 14.3 ppm for 24hours/day over five days for a period of 24 months. The exposure resulted in formaldehyde-induced lesions of rhinitis, epithelial dysplasia and squamous metaplasia in the nasal and tranchial region of both groups of rats and mice. The distribution of the lesions was concentration dependent. These lesions were in all the exposed groups of rats and intermediate and high exposure groups of mice.[26]

Similar studies of induced squamous cell carcinomas were observed on nasal cavities conducted by other researchers on animals.[26,27,28] These results show that formaldehyde may cause cancers in animals.[9,29] There were other negative results that showed no carcinogenic effect of formaldehyde on animals conducted by Kerns *et al* and Dalbey on mice and hamsters respectively.[26,30]

The study on chronic toxicity of formaldehyde administered orally to 20 male and 20 female Wistar rat groups resulted in erosions and ulcers in fore stomach and glandular stomach. The glandular hyperplasia with or without hyperkeratosis and downward growth of basal cells was observed. The study found that there were no significant differences in the incidences of any tumors among groups of both sexes. The no observable effect level at 0.02% formaldehyde in drinking water (10mg/kg body wt./day) was also concluded based on the results.[31]

1.6 Human studies

Humans may be exposed to formaldehyde through various sources, tissue fixation, tobacco smoke, automotive emissions and many products containing formaldehyde.[7] Formaldehyde causes genotoxicity, which is manifested in the DNA damage, cell mutations and tumors in experimental studies of human and animals. Inhaled formaldehyde is very reactive with the membrane of the nasal and oral mucosa. The human exposure to atmospheric formaldehyde even at exposure levels below exposure limits causes many fold increased level breakage of micronuclei and chromosomes in the oral mucosa. This cytotoxic and genotoxic effects may be experienced through interaction with endogenous cellular constituents such as glutathione, resulting in altered redox (Reduction-oxidation) state and gene transcription or inhibition of DNA repair.[7,32]

Concentrations below genotoxic levels in humans lower the significant dose-effect of other mutation-inducing agent, which implies that formaldehyde can increase the genotoxicity of chemical and physical agents in a synergistic manner.[33-35]

There has been some evidence that formaldehyde can be a neurotoxin to occupationally exposed workers that may result in neurobehavioural disorders such as insomnia, lack of concentration, memory loss, mood and balance alterations as well as the appetite loss. These neurobehavioral disorders were more confined to the histology workers. However, the attributions of the disorders to formaldehyde alone are complicated by co-exposure to other chemicals such as xylene, toluene and chloroform. In these studies, the workers were asked to crudely recall time spent using formaldehyde and no verification of the crude measures by which exposure to formaldehyde was distinguished from other solvents.[36-41]

Some researchers have found a link between formaldehyde exposure and respiratory organ cancers of different types and its decreased pulmonary function effects. [42-46] Partanen et al found the statistically increased risk for respiratory cancers (cancers of the trachea, bronchus, lung, pharynx, buccal mucosa) due to exposure levels, duration of exposure, cumulative exposure and the duration of repeated exposure to peak level in his study. [47] This cohort study on the industrial workers observed a slight but significant increase of mortality due to lung cancer. However, many other studies conducted on this group of workers shows no evidence of lung cancer due to exposure to formaldehyde except in the presence of other substances.[48]

The studies conducted to observe the formaldehyde occupational exposure effects on the pulmonary function shows evidence that support the adverse heath effects while some studies shows no heath effects for chronic occupational exposure. Some studies reported a reduction of up to 12% in parameters of lung function (e.g., forced vital capacity, forced expiratory volume, forced expiratory flow rate) to workers employed in chemical, furniture and plywood.[49-52] The health effects were shown to be transient over work-shift and reversible over short period of exposure (e.g 4 weeks). The health effects were more obvious among smokers than non-smokers.[50] Other studies indicated a dose-response relationship and a reduced lung function to workers exposed to formaldehyde at levels of 0.3 ppm or greater. However, a number of large studies conducted were the exposure to formaldehyde was >2 ppm indicated no evidence of diminished lung function to workers in wood, resin and funeral service industry.[53,54,55]

The concentration-response to relationships for the DNA-protein cross-linking, cytotoxicity, proliferation and tumors were found to be very non-linear and increased significantly at concentration at or above 4 ppm for rats. [56,57] Shaham et al found that the cellular proliferation increased considerably when concentrations are greater than 6 ppm for humans and these concentrations amplifies the genotoxic effect of formaldehyde. [58,59] Oliver Schmid and Gunter Speit conducted the research on the genotoxic effect of formaldehyde in human blood and found that the cytogenetic effects of formaldehyde are very unlikely to occur in blood cultures of exposed human subjects. [60] *Arabidopsis thaliana*-line transgenic for GUS recombination substrates was used to study the genotoxicity/mutagenicity of formaldehyde, and the results showed that formaldehyde exposure significantly increased the induction of homologous recombination in growing plants, but not in dormant seeds. [61]

In one large cohort study of industrial workers exposed to formaldehyde, the researchers evaluated mortality from solid cancers among 25,619 employees employed in formaldehyde-producing or using facilities in the United States of America (USA). The study found the evidence of exposure response relation with the mortality from nasopharyngeal cancer among the employees in these industries.[62] Another cohort study in the USA on the mortality NFDA members found similar results. The study was conducted among 6,651 dead subjects in this industry, covering a period from 1975 to 1985.[63] Many other studies including meta-analysis studies found the link between formaldehyde exposure and nasopharyngeal cancer. [64-66] A meta-analysis of formaldehyde exposure and upper respiratory tract cancers study by Collins et al also found no statistically significance between formaldehyde exposure and nasopharyngeal cancer. [67]

There are studies that have shown mortality due to myeloid leukemia in the workers exposed to formaldehyde. This was evident among embalmers, funeral parlour workers, anatomists and pathologist. [68] The studies were done to evaluate the causal relationship between formaldehyde and leukemia. These studies could not find causal association that resulted in excess mortality to leukemia due to exposure to formaldehyde.[69]

A case control study was conducted to investigate the causal relationship between the formaldehyde exposure and sinonasal cancer using a pooled analysis. The 12 previous studies of employees working in the wood or leather dust industry with exposure to formaldehyde were used. The study showed an increase in risk of sinonasal cancer.[70] In the cohort study by Pinkerton, the findings was that there were no increased risk of sinonasal cancer due to exposure to formaldehyede.[71] Other cohort studies found no excess of sinonasal cancer in industrial workers using or working in the formaldehyde exposed environment.[65,66]

There are studies that have found threat of occupational asthma as a result of exposure to formaldehyde.[72] On the contrary, there are many published studies reported no relationship between formaldehyde and cancer or induced asthma among people exposed to formaldehyde.[73,7] Some reports suggested that the development of bronchial asthma after formaldehyde exposure may be due to immunological mechanisms which may result in the adverse effects on the pulmonary function.[75] However, more research finding has indicated the exposure to formaldehyde is unlikely to be association with the suppression of the immune system.[76] However, animal studies have shown that formaldehyde exposure may enhance their sensitisation to inhaled allergens.[77]

Epidemiological studies conducted to evaluate the potential effects of formaldehyde exposure to reproductive and developmental effects in animals have not found or shown to occur to occupationally exposed individuals. The epidemiological studies indicated no clear evidence of increased risk of spontaneous abortion as a result of inhalation of formaldehyde by either paternal or maternal occupationally exposed individuals. Similar results were observed in animals. [78]

A 2005 prospective cohort study in Epidemiology was conducted on about 1.2 million US men and women participants. The finding linked the risk of formaldehyde occupational exposure to amyotrophic lateral sclerosis disease (ALS). Also, elevated mortality was found among women machine assemblers. Elevated ALS mortality was found to be high among male programmers and laboratory technicians but no evidence of increased mortality risk found among farmers, electricians and welders in the study. Previous case controlled studies conducted found an elevated risk in ALS among the welders, farmers, and electricians. [79]

On recent studies of formaldehyde on pathology workers, chromosomal aberrations (CA) were slightly lower in comparison with the group exposed to formaldehyde and solvents, which was attributed to a different rate of elimination of damaged lymphocytes as a consequence of formaldehyde-induced apoptotic activity.[80] Formaldehyde mediated apoptosis in lung epithelial cells by decreasing peroxiredoxin 2 protein via p38 mitogen activated protein kinase (p38 MAPK). [81]

formaldehyde is classified as a group 1 carcinogen in humans based on the evaluation by IARC formaldehyde of all previous studies conducted on formaldehyde on both animals and humans and their findings.[2,3,4] It is also classified by both the American Conference of Governmental Industrial Hygienists (ACGIH) and National Institute for Occupational Safety and Health (NIOSH) due to the conclusive evidence of formaldehyde mutagenecity in animals and its carcinogenic features as a suspected human carcinogen.[2, 4]

1.7 Exposure limits for formaldehyde

The acute effects of formaldehyde on human at levels above 5ppm is an intolerable irritation of the eyes and respiratory tract, and at 10ppm and above, a choking sensation occurs.[2] According to Fasset and Patty, concentration levels above 50 ppm, even at short duration, can cause serious injuries to the eyes and the respiratory organs.[29] Levels of formaldehyde higher than 20ppm are classified as Immediately Dangerous to Life or Health by NIOSH.[82]

There are various national and international standards used to protect the employees exposed to formaldehyde during their work. The Occupational Safety and Health Administration Permissible Exposure Limit (OSHA PEL) is 0.75 ppm for the 8-hour Time-Weighted Average (TWA) and the short term exposure limit (STEL) of 2ppm with the Action Level of 0.5 ppm. The NIOSH Recommended TWA is 0.016 and the 0.1 ppm for 15 minutes ceiling limit. The ACGIH threshold limit value (TLV) has a ceiling limit of 0.3ppm and the South African standard for STEL and TWA OEL-RL (Occupational Exposure Limit-Time Weighted Average Recommended limits) is 2ppm. In terms of South African Legislation on Occupational Health and Safety, the level of formaldehyde should be below the 2ppm STEL OEL-CL as (occupational exposure limit ï control limit for short term exposure limits) recommended by the Hazardous Chemical Substances Regulation of Occupational Health and Safety Act, No 85 1993.[4,83]

The study by Arts et al concluded that an indoor air level of 0.1 ppm (0.12 mg/m^3) formaldehyde can be considered safe and appropriate level. This was in contrast to the European Commission recommended guideline of 1εg/m^3.[84]

1.8 Problem Statement/Motivation

This study measured formaldehyde levels (for personal, task and environmental exposures) using shadow sampling. The study reported:

1. The exposure levels of each task and define the most problematic tasks and jobs categories in terms of exposure levels.
2. Personal exposure levels and
3. Environmental (Static) exposure levels

During the use of formalin in the Pathology Section, a significant amount of formaldehyde is dispersed into the general work environment. Research has shown that during the process of dissection, formaldehyde vapours/gas/fumes are emitted into the immediate ambient environment, which results in exposure of laboratory personnel.[85,86,87,88,89] It is thus expedient that personal and environmental exposure levels be continually assessed in workplaces where formaldehyde is used. The exposure levels observed in the settings was compared to the occupational exposure limit (OEL) recommended by the Hazardous Chemical Substances of Occupational Health and Safety Act, No 85 1993.[83] The measured exposure levels may help to suggest a need for epidemiological studies to assess the health effects of exposure.

In laboratories using formaldehyde, if engineering controls are non-existent or can poorly control the formaldehyde levels; employees will be exposed to the gas. The Pathology Section is currently moving into a new custom-designed facility and a number of extraction ventilation and other engineering control measures have been included in the specifications and designs of the new laboratory. This study will also help to determine the effectiveness of this newly installed ventilation system (as part of engineering control) in reducing the formaldehyde ambient levels below the OEL. The effectiveness was done through measuring formaldehyde ambient levels and the face velocity. These measurements will be respectively compared to OELsô and recommended face velocity for volatile organic vapours and formaldehyde.

Previous occupational hygiene formaldehyde exposure assessment studies conducted in the old Pathology Section using a Miran IB Portable Ambient Air Analyser Spectrometer and Draeger indicator tubes, revealed high concentrations of formaldehyde of over 2ppm OEL-

TWA.[87,88] However, the data collected was not sufficient to properly quantify exposure by tasks.

The study was supplementary to previous studies and serve as a reference for other similar studies in South Africa. Currently, there are no published comprehensive exposure assessment studies that have been done to measure formaldehyde levels in any Pathology Unit in South Africa. A study by JD Ossthuizen[3] had limited number of samples to make any conclusive evidence and did not measure peak values.[2] Previous studies only measured ambient levels and it is beneficial to measure personal exposure, environmental and peak values and assess sources of variability. [87,88]

This study will also be used to fulfill the requirements for the Witwatersrand University Masters in Public Health (Occupational Hygiene) degree for Mr.Hlosi Ntsuba.

1.9 Potential benefits to occupational health

This study will measure formaldehyde levels and assess how measured levels compare to OEL-CL STEL and OEL-CL TWA. This is important to determine if the exposure of employees to formaldehyde in the pathology unit is below the Occupational exposure limit-Control limit for formaldehyde needed to comply with the Occupational Health and Safety Act No.85 of 1993 Regulations for Hazardous Chemical substances.[83]

This study will help as a baseline for further studies assessing exposure to formaldehyde in the laboratory or other work environment in general industries. These studies are of importance either for control or epidemiological assessment of the health effects of formaldehyde. The findings and recommendations from the study will also help to support the pathology unit mandate of improving the health of the its employees.

1.10 Aim

The aim of this study was to assess formaldehyde exposure levels in a pathology laboratory unit.

1.11 Objectives

The objectives of the study was to:

1. Describe the work tasks and tasks involving the use of formaldehyde in the Pathology laboratory unit.
2. To learn to use the formaldehyde meter and shadow sampling technique.
3. To measure exposure to formaldehyde during these tasks.
4. To compare the measured formaldehyde short -term exposure limits OEL-RL and 8-hour TWA OEL-RL to national and international standards.
5. To assess the effectiveness of existing engineering/ventilation system control methods where it is installed and compare it to accepted standards.
6. To provide recommendations for the improvement of exposure controls where relevant.

CHAPTER 2

Methods

2.1 Study design

This study is a descriptive cross-sectional study. The study involves two parts

a) Part A - Job description

b) Part B - Exposure assessment (made up of three stages)

2.2 Part A - Job description

For part A, all the tasks involving the use of formaldehyde in the cardio respiratory organ examination in the Pathology Laboratory were studied and described.

There are two pathologists working in the cardio-respiratory laboratory with three laboratory assistants and three medical technologists. There are twenty-eight (28) task categories involving the use of formaldehyde. Certain tasks categories require two or three people, all doing different tasks and/or activities during their execution. The total tasks occurring at the same time may be two or three depending on the number of people involved. All these tasks are listed below.

Table 2.1:A list of different tasks categories performed by Pathology cardio-respiratory laboratory

Task	Responsible group for task	Description of task
1	Assistants	Receiving cardio-respiratory organs
2	Technologist	Transfer of cardio-respiratory organs a) Writing up the numbers, lung conditions etc
3	Assistants	Transfer of cardio-respiratory organs b) Helping with opening, lifting and readout of information inside the red delivery boxes
4	Assistants	c) Opening and transferring organs into fresh formalin white buckets ï Assistant 2
5	Assistants	Inflating the cardio-respiratory organs
6	Assistants	Preparation of cardio-respiratory organs before

		examination a) Removing formalin and replacing with water
7	Assistants	Preparation of cardio-respiratory organs before examination b) Removing water before dissection
8	Assistants and Technologist	Checking tools and PPE for pathologist before examination
9	Pathologist	Examination of cardio-respiratory organs a) Lungs diagnosis - Pathologist
10	Technologist	Examination of cardio-respiratory organs b) Recording of diagnosis - Technologist
11	Assistants	Examination of cardio-respiratory organs c) Weighing, cutting, sorting & (un) repacking of cardio-respiratory organs
12	Assistants	Cleaning of tools and floor after cardio-respiratory organs examination
13	Assistants	Refilling of plastic bags with formalin after examination
14	Assistants	Transfer of cardio-respiratory organs after examination from round buckets to small square red lids buckets
15	Assistants	Removal to storage of cardio-respiratory organs
16	Assistants	Labeling
17	Assistants	Filing
18	Technologists	Loading citadel machine
19	Assistants	Filling of empty plastic bags with formalin for clients
20	Assistants	Transfer of waste boxes to main storage room
21	Assistants	Manual preparation of Formaldehyde
22	Assistants	Looking for photography buckets cases
23	Assistants	Looking for special cases inside the buckets
24	Technologists	Taking of photographs for special cases
25	Assistants	Cleaning ï pack and sort
26	Assistants	Washing white round buckets

27	Assistants	Discarding of cardio-respiratory organs
28	Assistants	Dispatching

The study described the jobs and the associated tasks of each job category. This included:
A priori job description ï As per Standard Operating Procedure (SOP)
Observational job description ï These were done in short summary as per researcherõs observation of tasks. All the tasks involving formaldehyde were be described.

2.3 Part B

2.3.1 Exposure assessment

The sampling strategy employed for this study involved three stages. All jobs and associated tasks were studied. Personal samplings were done by selecting one staff member for each job category and sample him/her for three days while performing his/her job. The whole sampling period lasted for about sixteen weeks.

2.3.2 Stage 1

This stage involved measuring the exposure level of formaldehyde of all tasks carried out in the laboratory by the personal shadow sampling technique. The shadow sampling method involves the sampling done by holding sampling media in the breathing zone of the person being sampled. The results obtained were used to identify and determine the most exposed tasks and job category group(s).

Each task was measured 3 times (on 3 different days) to get a reliable estimate and assess any variability in exposure including discarding of cardio-respiratory organs, which was estimated to be done at least two times a year.

This measured the formaldehyde exposure levels associated with each task and help to identify high-risk tasks that need to be controlled.

2.3.3 Stage 2

One person from each job category was selected and followed for the working day while performing his/her tasks. The personꞌs tasks were recorded. The tasks peak values were measured. This helps to confirm high-risk jobs and estimate 8-hours exposure levels using both OEL-TWA and peak values.

2.3.4 Stage 3

Ambient formaldehyde concentrations were measured and compared to National and international Occupational exposure limits - time weighted average (OEL-TWA) limits to estimate employeeꞌs exposure.

The static samples were taken for three days in all the working areas used by the cardio-respiratory laboratories staff. In three different days, additional samples were taken along the corridor, the laboratory areas and different storage areas to check exposure levels and possible leaks of formaldehyde outside these open and enclosed laboratories used to perform various tasks for cardio-respiratory examination.

This is important since the employeeꞌs work in an enclosed laboratory room/area supplied with fresh air from outside and the ambient level of formaldehyde in the area will be directly related to their background exposure while working in the enclosed area. This helped us assess if the ventilation installed helps in reducing the levels of formaldehyde in the atmosphere and if there were any formaldehyde leaks from the laboratory to the employeeꞌs offices found in the same floor as the laboratories.

2.3.5 Physical Measurements

During part A and B, the laboratory temperatures, humidity levels were measured to help in the assessment of the ventilation system and interpretation of formaldehyde levels. These measurements were automatically measured by formaldehyde instrument as it measures the formaldehyde concentration. The readings were data logged together with each reading of formaldehyde concentration. These measurements were done continuously daily and recorded.

2.4 Sampling equipment

This section describes the instruments that were used in this study.

2.4.1 Formaldemeter

The Formaldemeter uses the electrochemical sensing technology to determine the concentration of formaldehyde in the air. The electrochemical formaldehyde sensor has two metal electrodes with the electrolyte. Air is drawn into the Formaldemeter *htv* probe using internal pump. As air is drawn in, there is a small voltage created as a result of the electro oxidation of formaldehyde contained in the air drawn in which is deposited on one of the two noble metal electrodes, which is catalytically active. The magnitude of the voltage produced is directly proportional to the concentration of the formaldehyde in the air drawn. This voltage signal is then sent to amplifier and the output is sent to liquid crystal display (LCD) of the formaldehyde instrument in either ppm or mg/m^3.
The AMS-2 is connected to the Formaldemeter to give the instrument the data logging capability. If the AMS-2 data logger is connected to the Formaldehyde instrument, the signal is then sent to the LCD display of the AMS-2 data logger. The Formaldemeter connected to data logger is capable of measuring the concentration of formaldehyde in air semi-continuously automatically.

Formaldemeter has been reported to instantaneously and accurately measure formaldehyde in the air over a range of concentration.[10] The range and accuracy of results depends on the maximum range value of the formaldehyde sensor used. For this instrument the maximum concentration that can be measured was 10ppm. Any result equal or above to 10ppm or less that 0.05ppm detection limit were not included in calculation of peak means as they were regarded as outliers. In essence, there could have been exposures equal or above 10ppm which were not included in our calculation.

Formaldemeter (direct reading instrument) was used for taking short term exposure levels and peak or ceiling values for different tasks. The instrument was calibrated before and after sampling with the formaldehyde calibration solution of known concentration as recommended by and sourced from the manufacturer. The measurement was done using personal shadow sampling method (see nomenclature for shadow sampling definition).

Formaldemeter *htv* model (referred here as Formaldemeter) with serial number F4936, was used to measure both temperature, to help in the assessment of the ventilation system and interpretation of formaldehyde levels).

Formaldemeter works by sampling 10ml of the ambient air for 8 seconds and takes 1-3 minutes to analyse the sample depending on the previous results. The results will be data logged for each task. The sampling process for area sampling and personal exposure per group was set to be continuous for eight or more hours and in the process data logged for future analysis. The short-term exposure during the tasks was set for 15 minutes Short Term Exposure period consecutively until the task was finished.

Formaldemeter connected to AMS-2 is designed to measure both temperature and humidity and display them. It operates most accurately in the temperature range of 10-30°C and humidity range of 30-60%rh. It is however capable of compensating for accurate measurement even if the temperature and humidity parameters are outside this accuracy range.

2.4.2 Veloci Calc Instrument

Veloci Calc model 8388-M-GB, serial number 97030409(REV S) is a direct reading instrument. It measures the air velocity by allowing the air cooling of the heat probe at the end of probe as atmospheric air passes over this heated probe. The electrical current generated and required to maintain the temperature of the probe is directly proportional to the air velocity. The air velocity reading is displayed in the LCD of the Velocity Calc as a reading in either meters per second (m/s) or feet per minute (ft/min).

2.4.3 Accubalance

Accubalance air capture hood (referred to as Accubalance), model 8370-M-GB, serial number 97030449(Rev N), is designed to measure the air flow to or from the grilles or diffusers outlets. It consists of a fabric hood with electronic meter molded into plastic base. The base contains a flow sensing manifold in the molded plastic. The flow sensing manifold has twenty four (24) hot-film sensors which contain strategically located flow sensing ports that measures the air flow with high degree of accuracy even in non-uniform flow conditions.
The Accubalance is temperature compensated to display the readings in l/s or m^3/min under standard temperature and pressure conditions.

2.4.4 Micrometers

This is the instrument used to measure distance in millimeters accurately up to two decimal points. This instrument was used in the measuring diameter of basin punched holes (round) of different ventilation tables used on the workstations that suck surrounding air into the ventilation system. Before the micrometer was used, the micrometer readings were calibrated using a normal ruler to verify the micrometer accuracy.

2.5 Procedures

2.5.1 Calibration

The formaldehyde calibration standard was used to calibrate the Formaldemeter instrument. For background purpose, a different office environment more than 100 meters away from the pathology section within the same building was selected and sampled prior to beginning of sampling in the pathology unit. The five minutes to fifteen minutes background readings were taken for each measurement in a non-exposed environment from the pathology unit in the same building. The background readings were taken and recorded daily in the morning before the start of every monitoring process in all the three stages. The calibration was done with the formaldehyde calibration standard daily and the results were not accepted if the reading was more than the 0.05ppm. In the afternoon, a calibration check was performed to ensure the instruments performance has not changed through the day.

2.5.2 Face velocity measurements

With every measurement done on the day, where ventilation system exists, face velocity were taken and where possible, compared to the manufacturer's specification. The instrument was placed on the grills of the ventilation system and about 9 to 12 readings were taken and averaged to obtain unit value for face velocity. The velocity was able to tell us how the system is performing in relation to the accepted standard specifications for designing ventilation to control Formaldehyde.

2.5.3 General air speed measurements

General room air speeds (velocity) were taken by measuring air speed in all three dimensions inside the room-using anemometer and averaging the results. At least two measurements were taken in every direction for a period of approximately 3 minutes. The measurements were taken two times a day, one in the morning and another one in the afternoon. The daily measurements were also averaged to give an average airflow for each day the measurements were taken. The measuring of air velocity in all direction was done because the overall air direction was difficult to determine in the laboratories, general work areas and corridors.

2.5.4 Table basin velocity measurement

The velocity in each basin four sides was measured at about 30 cm points or once on each of the side depending on the drainage basin side length using Velocicalc instrument.

All the instruments Velocicalc, Accubalance and Formaldemeter used for the research were allowed to acclimatise to the surrounding environment temperature for 15-30 minutes prior to sampling.

2.5.4 Supply diffusers volumetric measurements

The Accubalance was first turned on and the appropriate flow section of supply air was selected. To measure air volumetric flow, the Accubalance was pressed against the parameter edges of the diffuser so as to form a complete seal. The Accubalance was allowed to take readings for about 30 seconds and the reading was displayed and recorded. This was repeated three times and the recorded readings averaged for every diffuser. The Accubalance was kept in place against the edges of the diffuser during the entire sampling interval of 30 seconds and the average-measurement appeared on the display.

2.6 Quality Control

The National Institute for Occupational Health (NIOH) Occupational Hygiene Section is the approved inspection authority for measuring physical, chemical, biological and ergonomic stressors/hazards. The services of an internal certified occupational hygienist staff member were used to verify the sampling method before and after sampling. When verifying the results, the staff member considered the instrument used and its performance, calibration procedures, measurements procedures, representativeness of samples, accuracy and reproducibility of results.

2.7 Statistical analysis

Data collected for this study were captured in Microsoft Excel and transferred to Stata 10 (StatCorp, Texas) statistical package where all statistical analyses were carried out. Simple descriptive statistics (including means, medians, proportions) for formaldehyde exposure levels were computed and results were presented in tables and figures. To test for significant difference in measurements, data were log-transformed and an analysis of variance (ANOVA) was conducted on log-transformed data. Between task and within-task variability in exposure were also assessed. P-values less than 0.05 were interpreted to mean statistical significant differences.

2.8 Limitation

The Formaldemeter connected to the AMS-2 data logger instrument cannot measure the formaldehyde accurately below 0.05ppm. However, this detection limit is way below the OEL. However, during calibration (not reported) the readings below these levels were recorded when instrument background readings were being done at more than 100m away from the pathology laboratory. During transfer, four tasks take place at the same time in the same laboratory. Due to limited number of instrument and budget, only one instrument was used to measure all four (4) tasks during the transfer process on different days, which may increase the actual variability between these tasks as variability may be influenced by weather conditions and difference in daily working pattern by the same individual.

The formaldemeter htv instrument was designed as an area-monitoring instrument but was adapted for measurement of personal exposure in this study using shadow sampling. Those task that involve a great deal of movement may be under sampled or over sampled because of the limitation of following every move by participating study subjects. Hence the results should be treated with caution. However, in order to counter this limitation, where great movement was anticipated, the instrument was attached to the study subject to minimize the effect of movement.

Lastly, the instrument does not monitor the levels of formaldehyde continuously but take spot samples at least every 2 minutes when connected to the AMS-2 monitoring station. Where readings were very high, the instrument may take anything up to 10 minutes before readings are displayed and another spot sample is taken. In order to simplify the results for analysis, the results were assumed to remain constant for the duration of sampling until the next spot sample is taken. This may underestimate or overestimate the formaldehyde exposure levels because of the lapse period between the samples. This underestimation or overestimation of formaldehyde exposure levels may be more pronounced for high reading results where the response time is extended up to 10 minutes between sampling.

2.9 Ethics Approval

Participation in the study was voluntary and a signed written consent was obtained from each participant. No questionnaire was administered and no test of any kind was done on participants. Each participantõs was given unique study number to ensure all information is confidential. The study results are treated with care and only anonymous results will be released and published. The ethical approval was obtained from the Ethics Committees for Human Subjects of the University of the Witwatersrand (M070430).

2.10 Learning the Instrument

The AMS-2 Aldehyde Monitoring Station is a portable self-contained data-logging unit that automates the operation of Formaldehyde PPM handheld gas detectors, enabling them to be used as semi-continuous monitors (see fig 2.1)

The researcher has learned to calibrate, monitor with formaldemeter htv as a stand alone instrument or connected to the AMS-2 with data logging capability. He is able to set parameters for the system and motoring setup to get final summary reports in a format he need.

Fig. 2.1: AMS-2 Aldehyde Monitoring station, Formaldemeter htv instrument and the Formaldemeter htv calibration set.

The features of the AMS-2 include the paper tray for thermal printer, LCD to display readings and important operational messages,; keypad for displaying preset parameters or changing the parameters as required. The keypad parameters used on AMS-2 to ensure quality of results are shown below:

Table 2.1: AMS-2 keypad functions

Number On AMS-2 keypad	Function
1	Set time
2	Set date
3	Paper Feed
4	Data logging
7	View data

It was important that date, time and data log correspond to the task being monitored for traceability of results.

The general systems and monitoring sessionꞌs operation of the set are described in the system setup flowchart and monitoring session setup flowchart respectively (See appendix 3). In the systems setup flow chart, option to modify alarms was never used, as it required the use of external alarm, which was not available or necessary to use for the purpose of our monitoring. Typical examples of report printed for and data logged for the monitoring are shown below. The reports are for settings, periodic, final summary and calibration results.

a) 

www.ppm-technology.com
Time : 08:06:41
Date : 19/02/08
Base Station Settings:
Continuous Sampling
Duration 1h 00m
Meter Mode : AREA
Start : 10.0 Seconds
End : 60.0 Seconds
Filter : Enabled
Scale : 20%
Rh Limit : 30%
Peak Time 6.7 Seconds
Pump Run : 1.7 Seconds
HHU Short Hold 0
Status reports enabled.
Final graph enabled.
Reports issued once
every 15 minutes
Summary Print Every
Session.
Auto-repeat enabled.
Overwrite On Full

b) 

Time : 14:35:36
Last STEL = 0.577 ppm
Periodic Min Temp 18.5
Periodic Max Temp 20.2
Periodic Min Rh 48.6
Periodic Max Rh 54.0

Time : 14:53:46
Last STEL = 1.548 ppm
Periodic Min Temp 17.8
Periodic Max Temp 18.1
Periodic Min Rh 56.4
Periodic Max Rh 59.2

Time : 15:09:17
Last STEL = 1.662 ppm
Periodic Min Temp 17.4
Periodic Max Temp 17.7
Periodic Min Rh 58.3
Periodic Max Rh 59.0

c) 

FINAL SUMMARY
SAMPLING WAS ABORTED!
Time : 16:08:54
Date : 18/02/08
Statistical summary:-
Sampling commenced at
Time : 15:37:41
Date : 18/02/08
Duration 0h 27m
Peak Conc. = 5.763 ppm
Last STEL = 4.483 ppm
8 hour TWA = 5.621 ppm
Session Min Temp 17.5
Session Max Temp 18.4
Session Avg Temp 17.8
Session Min Rh 52.5
Session Max Rh 56.5
Session Avg Rh 54.9

Fig 4.2: Typical report for a) settings with calibration result shown, b) periodic report and c) typical final summary report

Chapter 3

Results

This chapter presents the result of this study in five parts:

3.1 Part 1 ï Tasks observation
3.2 Part 2 ï Formaldehyde exposure assessment by job-type
3.3 Part 3 ï Formaldehyde exposure assessment by tasks
3.4 Part 4 ï Area formaldehyde measurements
3.5 Part 5 ï Physical measurements

3.1 Part 1 – Tasks observations

This part presents the descriptions of the various tasks in the laboratory as observed by the researcher (table 3.1). Observations were made on all laboratory tasks in relation to the standard operating procedures (SOPs). It should be noted that not all tasks had an SOP. Some SOPs were still being developed. The numbers of various tasks done by each job categories/group were found to be 23 tasks for assistants, 5 tasks for technologists and 1 task for pathologist(s).

Table 3.1: Observational results for various tasks

Task	Responsible Person	Description of task	Observations
1	Assistants	Receipt of cardio-respiratory organs	The SOP is followed with minor deviation. Receipt lungs were not immediately checked.
2	Technologists	Transfer of cardio-respiratory organs a) Writing up the numbers, lung conditions etc	Done as per SOP
3	Assistants	Transfer of cardio-respiratory organs	Done as per SOP

		b) Helping with opening, lifting and readout of information inside the red delivery boxes	
4	Assistants	c) Opening and transferring organs into fresh formalin white buckets	Done as per SOP
5	Assistants	Inflating the cardio-respiratory organs	Done as per SOP
6	Assistants	a) Removing formalin and replacing with water (Rinsing organs)	Done as per SOP
7	Assistants	Preparation of cardio-respiratory organs before examination b) Removing water before dissection	As per SOP with slight modification. The drum may be any distance from the preparation area and the assistant may have to walk to pour dirty water into it. The lungs are not removed but left in the buckets.
8	Assistants and Technologists	Checking tools and PPE for pathologist before examination	As per the SOP. Sometimes one person, either a technologist or assistant does the tool checking after the assistant prepares them.
9	Pathologists	Examination of cardio-respiratory organs a) Lungs diagnosis	As per SOP
10	Technologists	Examination of cardio-respiratory organs b) Recording of diagnosis	As per SOP

11	Assistants	Examination of cardio-respiratory organs c) Weighing, cutting, sorting & (un) repacking of cardio-respiratory organs	Slightly modified. At times he may be involved with doing the actual lung slicing. In between lung examination, assistant uses cotton wool to clean the surface for next cardio respiratory case. The cotton cloth used is put into the plastic used to store each of the examined cardio respiratory organ.
12	Assistants	Cleaning of tools and floor after cardio-respiratory organs examination	No SOP. The tools, bench and the floor are washed with phenol mixed with water. Phenol may be poured directly onto the floor or mixed with water before wetting the floor. The mop is used to clean the floor afterwards. At times, the cleaning is done while the bucket of sliced lungs is on the floor immediately after Pathologist examination. The assistant bends over to remove them thereby being exposed to formalin fumes. Small cuts of lungs and surface are cleaned with cotton cloth.
13	Assistants	Refilling of plastic bags with formalin after examination	As per SOP. Laboratory assistants prepare the plastic and strings. The formaldehyde is poured into plastic bags from the tap on the bench. The strings are used to tie the bags closed. These bags are then placed into white buckets to be given to clients.
14	Assistants	Transfer of cardio-respiratory organs after examination from round buckets to small square red	Done as per the SOP. SOP for this task is part of SOP for the lung examination.

		lids buckets	
15	Assistants	Removal to storage of cardio-respiratory organs	Part of the SOP for examination of the lungs by Pathologist. The transfer of lungs to storage for filling is normally done after cleaning and disinfections of the tools and floor. The organs are first transferred to the transfer room for labeling before they are sent for storage.
16	Assistants	Labeling	Part of the SOP for examination of the lungs by Pathologist. Done in the transfer room.
17	Assistants	Filing	No SOP. This involves packing the closed buckets from the trolley to the shelves while ensuring that they are stored in sequential order in the storage area.
18	Technologists	Loading citadel machine	No SOP. 1. Open the citadel 200 machine lid 2. Load the sample cassette onto machine 3. Lock the cassette into position using steel plate that is placed on top of loaded sample cassette. 4. Lower cassette into formalin container into the machine. 5. Close and put machines on. 6. When complete come and remove cassette.
19	Assistants	Transfer of waste boxes to main storage room	No SOP 1. Boxes sealed with hazardous tape all round. 2. Load boxes on to the trolley and move (with lift) to box weighing area

			3. Weigh first each box and record on weighing form. Repeat for other boxes. 4. Off load boxes into storage area. The storage door is kept closed at all times and key controlled by responsible laboratory manager.
20	Assistants	Manual preparation of Formaldehyde	No SOP 1. Opening 37% 5 liter formalin bottles and pouring into the mixing drum. 2. Pouring the 2 x 25 liters drum of water to mix with 37% formalin solution in the mixing chamber. 3. Allow proper mixing of water and formalin for about 2 ï 5 minutes. 4. Stop the motor and pump the mixture to the temporary storage for use during transfer or refilling of empty plastic bags for formalin. 5. Repeat step 1-4 until the required quantity is prepared.
21	Assistants	Looking for photography buckets cases	No SOP The technologist prepares and provides a list of case p-numbers to be retrieved from storage to assistant. Assistant use the list to check for the cases from storage area. Each case is removed from shelves and placed on the floor before being carried on the trolley to the laboratory. (If the storage is high up the shelves, stepladder is used).
22	Assistants	Looking for special cases (discarding)	No SOP Similar to looking for photography

		inside the buckets	cases above except that the cases are opened to confirm p-numbers for discarding once on the floor.
23	Assistants	Taking of photographs for special cases	As per SOP with slight modification. The photographs are sometimes taken during the week and not on Friday. The technologist may rarely do some functions of a laboratory assistant like putting back the lungs into the buckets or looking for the lungs cases inside the bucket.
24	Technologists	Cleaning, packing and sorting for special cases	1. Remove the red lid containers and move to a separate place on the shelf 2. Sort and pack the containers in increasing order on the shelf. 3. Clean the floor for spillages with mob once sorting and packing is complete.
25	Assistants	Washing white round buckets	No SOP The bucket are stacked together One bucket pulled out of the stack and washed with handy andy and steel wool inside the basin. Putting used water with Handy Andy into the next bucket and washing it Repeat until all buckets are washed.
26	Assistants	Refilling formalin plastic bags -clients	As per SOP
27	Assistants	Discarding of cardio-respiratory organs	As per SOP
28	Assistants	Dispatch	As per SOP

3.2 Part 2: Formaldehyde exposure assessment by job type

This part presents the formaldehyde exposure levels observed for each job type. The results are presented as:

1. Daily variation in formaldehyde exposure levels by job type
2. Short term exposure limits (STEL) by job type
3. 8-hours time-weighted average (8-hour TWA) by job type
4. Peak exposure levels by job type

3.2.1 Daily variation in formaldehyde exposure levels by job type

These are daily formaldehyde concentration exposure level for all three jobs types. The results were not normalised to 8-hour TWA but are the daily concentration of formaldehyde exposure levels**.**

Technologist

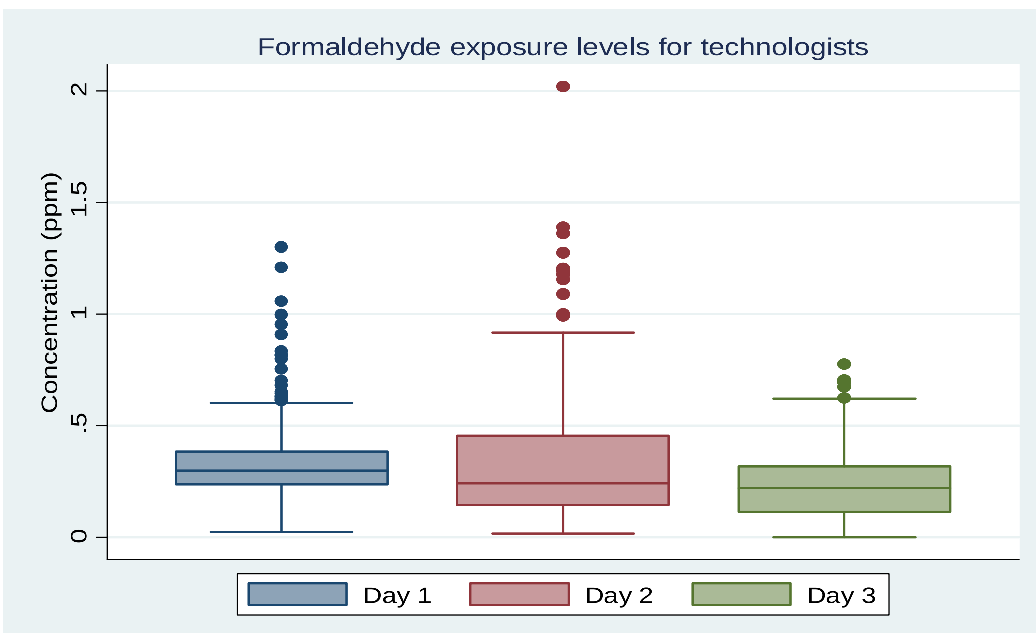

Figure 3.1: Box and whisker plot showing the daily formaldehyde exposure level for technologists for the three days of measurements

Figure 3.1 shows that on day one, 50% of the measurements for technologists were below 0.29ppm while on day two 50% were below 0.22ppm and on day three 50% was below 0.19ppm. Further analysis showed that their exposure levels varied significantly with day of measurement, with day three being significantly lower than day one and day two (table 3.2).

Table 3.2: Difference between daily exposure levels for technologists (log-transformed data)

Day	Mean (Standard deviation)	P-value for difference
1	0.33 (0.22)	Between 1 and 2 = 0.964
2	0.35 (0.31)	Between 2 and 3 = 0.001
3	0.25 (0.17)	Between 1 and 3 = 0.013

Assistants

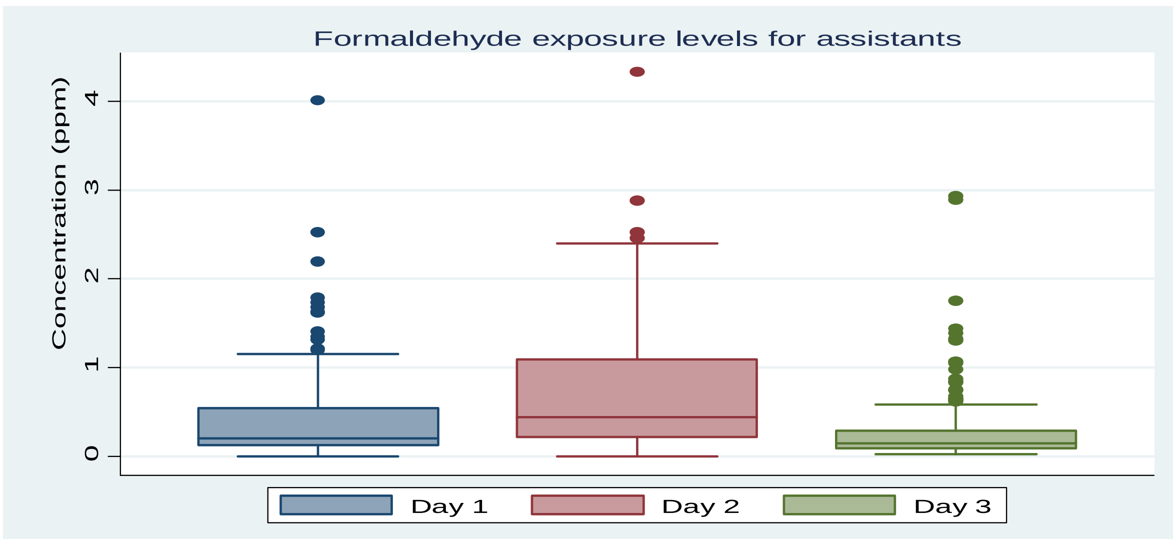

Figure 3.2: Box and whisker plot showing the daily formaldehyde exposure level for assistants for the three days of measurements

Figure 3.2 shows that on day one, 50% of the measurements for assistants where below 0.21ppm while on day two 50% were below 0.43ppm and on day three 50% was below 0.14ppm. Further analysis showed that their exposure levels varied significantly with day of measurement (table 3.3).

Table 3.3: Difference between daily exposure levels for assistants (log-transformed data)

Day	Mean (Standard Deviation)	P-value
1	-1.33 (0.94)	p< 0.001
2	-.812 (1.07)	p< 0.001
3	-1.76 (0.88)	p< 0.001

Pathologist

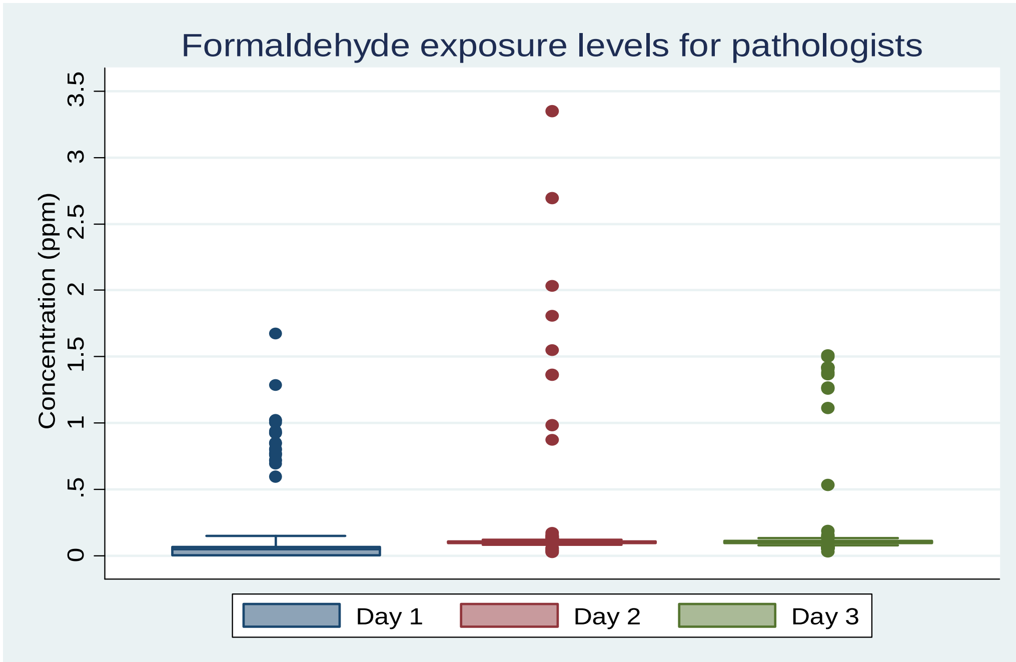

Figure 3.3: Box and whisker plot showing the daily formaldehyde exposure level for pathologist for the three days of measurements

Figure 3.3 show pathologistȇs daily exposure levels were similar for all three days with, 50% of the measurements on day one being less than 0.13ppm while for day two and day three, the medians were 0.18ppm. Further analysis showed that Pathologist shows no significant difference in exposure levels between days (Table 3.4). Exposure variation between days is not significantly different.

Table 3.4: Difference between daily exposure levels for pathologists (Log transformed data)

Day	Mean (Standard Deviation)	P-value for difference
1	0.11 (0.26)	Between 1 and 2 = 0.095
2	0.17 (0.38)	Between 2 and 3 = 1.000
3	0.168 (0.28)	Between 1 and 3 = 0.152

3.2.2 Variance structure of daily formaldehyde exposure by job type

Analysis of variance results for the daily exposure levels show that the between job variance (0.022) was lower than within-job variance (0.15), p-value < 0.001. The result indicates that there is more variation in exposure levels within jobs that there is between jobs. However, there is significant difference between job groups (table 3.5).

Table 3.5: Difference between exposures by job types

Group	Mean (Standard Deviation)	P-value for difference
Assistants	0.44 (0.55)	Between Technologist and Assistant = <0.0001
Technologists	0.31 (0.24)	Between Technologist and Pathologist = <0.0001
Pathologists	0.15 (0.31)	Between Pathologist and Assistant = <0.0001

3.2.3 Short term exposure limits (STEL) by job type

The red line represents the NIOSH STEL of 0.1 ppm and the green line at 2ppm represents the both South African (SA) OEL-STEL and OSHA STEL values.

While figure 3.4 shows the STEL values for each day of measurement, table 3.6 shows the mean STEL values for all three days. The STEL values for the three job types show that assistants are the highest exposed followed by pathologists. Based on the changes in nasal tissue in workers, the Agency for Toxic Substances and Disease Registry derived a chronic Minimum Risk Level (MRL) of 10 ug/m^3 or 8ppb.[90] However, the chronic reference exposure level (REL) for formaldehyde is lowest at 0.002ppm (2ppb/3µg/m^3). This value was based on no-observed-adverse-health-effects (NOAEL/LOAEL) of 32µg/m^3/26ppb for symptoms of irritation in workers.[91] Both the MRL and REL values are significantly lower than TWA values obtained in the study see table 3.6

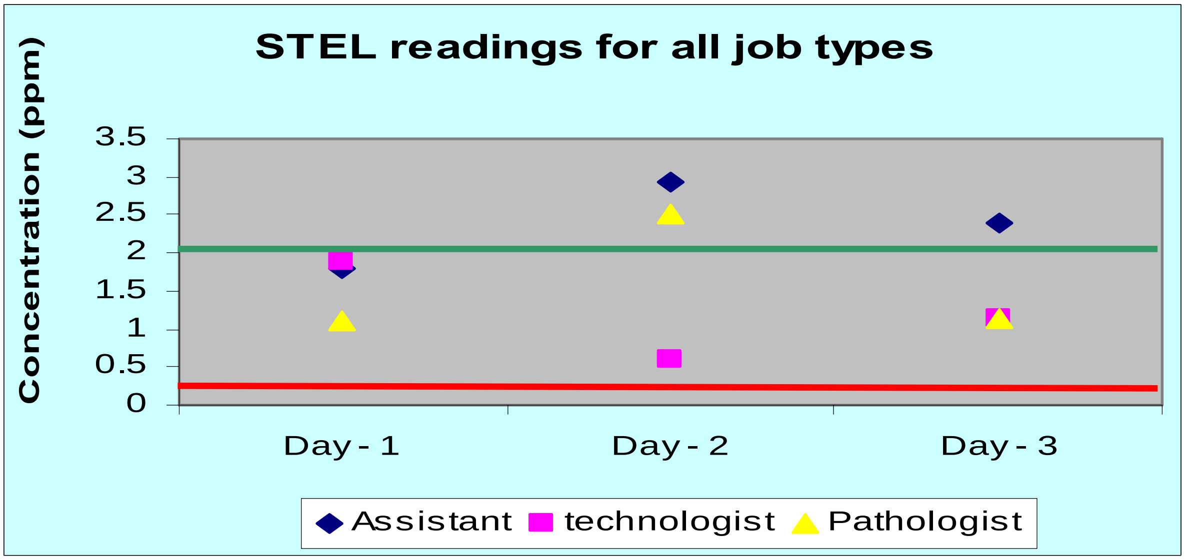

Figure 3.4: The STEL readings for all three types of job groups.

The least exposed group is the technologist. The comparison between the mean STEL values and different local or international SA OEL-STEL values shows that the two values for assistants and one of three values for pathologist were over the SA and OSHA STEL values respectively (table 3.6 and figure 3.4).

Table 3.6: Comparison of mean STEL values to national and other international standards

Short Term Exposure Limit (STEL) in ppm				
Job	**Mean STEL** (std dev)	**Mean STEL*> OEL-STEL**	**Mean STEL* > NIOSH STEL**	**Mean STEL*>OSHA STEL**
Assistant	2.37 (0.57)	2\3	3\3	2\3
Technologist	1.21 (0.65)	0\3	3\3	0\3
Pathologist	1.59 (0.79)	1\3	3\3	1\3

*STEL= The highest STEL value taken from 8-hour TWA for each of the three jobs

3.2.4 8-hours time-weighted averaged (8-hour TWA) by job type

All the individual day result for both the pathologists and the technologists were below the set limit for 0.75ppm (750pbb/920µg/m^3) 8-hour TWA (OSHA PEL-TWA) and 2ppm of the South African (SA) OEL-TWA formaldehyde standard. The results for the pathologist were below both the SA and the OSHA limit. None of the results were below the recommended TWA limit set by NIOSH of 0.016ppm. The OSHA PEL-TWA is based on reducing risk of cancer, eye, nose and throat irritation and sensitization on workers.[92] NIOSH limit of 0.016ppm(16ppb) was based on the threshold of reliable measurement at that time.[92]

Table 3.7: Mean 8hr-TWA results for different job categories

Job	Day1	Day2	Day3	TWA-average	TWA average> NIOSH	TWA average > OSHA PEL	TWA average > OEL- TWA
Assistant	0.58	0.86	0.37	0.60±0.25	3/3	1/3	0/3
Technologist	0.46	0.38	0.36	0.36±0.11	3/3	0/3	0/3
Pathologist	0.14	0.27	0.23	0.21±0.07	3/3	0/3	0/3

Table 3,7 shows that all three job categories were overexposed when compared to NIOSH recommended standard but only assistant were overexposed when compared to OSHA PEL limit.

3.2.5 Peak exposure levels by job type

Table 3.8: Peak value results and their comparison to ACGIH* ceiling limit

Peak values in comparison to ACGIH ceiling limit							
Job	**Day-1 Peak**	**Day-2 Peak**	**Day-3 Peak**	**Peak Mean (std dev)**	**Min Peak**	**Max Peak**	**Peak> ACGIH-CL**
Assistant	2.53	4.33	2.89	3.25 (0.95)	2.53	4.33	3\3
Technologist	2.09	0.78	1.30	1.39 (0.66)	0.78	2.09	3\3
Pathologist	1.67	3.35	1.51	2.17 (1.02)	1.51	3.35	3\3

* ACGIH ï American Conference of Governmental Industrial Hygienists

Assistants and pathologist had the highest peak values at 4.33ppm and 3.35ppm respectively. Also, the highest mean peak value was for the assistants and the lowest was for technologist.

3.3 Part 3 - Formaldehyde exposure assessment by tasks

3.3.1 OEL-STEL values for all tasks

For each task, the highest OEL-STEL reading was taken for each day of measurements. Mean STEL values were used to classify tasks into low, medium and high exposure groups using the South African standard of 2ppm. Values above 2ppm (>100% STEL limit) were classified as high exposure (Red); values between 1ppm and 2ppm (50-100% STEL) were grouped as medium exposure (Yellow) and those below 1ppm (<50%STEL) as low exposure group (Green) as tabulated in table 3.9. Acute REL for formaldehyde based on irritation of asthmatics is 0.74 ppm (74ppb) as established by World Health organisation (WHO) in 1989.[93]

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Table 3.9: STEL values for all tasks

Task	STEL1	STEL2	STEL3	STEL-Mean (std dev)	STEL MIN	STEL Max	
Receiving cardio-respiratory organs	0.12	0.04	0.81	0.32 (0.42)	0.81	0.04	Green <1ppm
Cleaning -	0.43	0.22	0.30	0.32 (0.11)	0.43	0.22	
Removing water from Lungs	1.28	0.57	-	0.93 (0.50)	1.28	0.57	
Recording of diagnosis	0.67	1.12	0.56	0.78 (0.30)	1.12	0.56	
Cleaning tools	0.74	1.03	0.88	0.88 (0.15)	1.03	0.74	
Organs removal to storage	0.19	0.21	0.19	0.20 (0.01)	0.21	0.19	
Waste box removal	0.15	0.22	0.19	0.19 (0.04)	0.22	0.15	
Dispatch	0.40	0.31	0.26	0.32 (0.07)	0.40	0.26	
Refilling formalin plastic bags - clients	0.65	0.62	1.02	0.76 (0.22)	1.02	0.62	
Checking tools before examination	0.12	0.20	0.27	0.20 (0.08)	0.27	0.12	
Loading citadel	0.02	0.04	0.03	0.03 (0.01)	0.04	0.02	
Inflating lung(s)	0.77	0.71	0.59	0.69 (0.09)	0.77	0.59	
Washing buckets	0.55	0.76	1.28	0.86 (0.38)	1.28	0.55	
Labeling	0.80	0.69	0.17	0.55 (0.34)	0.80	0.17	
Looking for special cases	0.26	0.21	0.20	0.22 (0.03)	0.26	0.20	
Transferring lungs from round to red lid buckets	3.89	0.90	0.38	1.72 (1.89)	3.89	0.38	Yellow >1ppm < 2ppm
Lung examination	0.90	1.90	1.64	1.48 (0.52)	1.90	0.90	
Transfer ï (Packing lung containers during Transfer) Helper assistant 2	1.21	1.96	-	1.59 (0.53)	1.96	1.21	

Transfer ï (Technologist recording sampling information)	1.27	1.78	1.69	1.41 (0.27)	1.78	1.27	
Refilling formalin plastic bags after lung examination	1.10	1.28	1.17	1.18 (0.09)	1.28	1.10	
Assisting pathologist with weighing, cutting and removal of organs	1.10	0.47	1.64	1.07 (0.59)	1.64	0.47	
Filing organs	0.53	0.18	2.45	1.05 (1.22)	2.45	0.18	
Removing Formalin from lungs	0.36	3.30	4.11	2.59 (0.50)	4.11	0.36	Red
Discarding	3.54	2.63	3.15	3.11 (0.46)	3.54	2.63	Ó2ppm
Manual Formalin preparation	2.29	2.49	7.19	3.92 (2.46)	7.19	2.29	
Looking for photography cases	2.44	4.71	3.31	3.49 (1.15)	4.71	2.44	
Transfer ï Assistant 1	9.17	4.78	1.88	5.28 (3.67)	9.17	1.88	
Taking photographs	2.44	2.80	1.36	2.2 (0.75)	2.80	1.36	

3.4 Part 4 - Area formaldehyde measurements

3.4.1 Peak values for all tasks

As in the classification of groups for STEL values a similar grouping was done using the ACGIH ceiling threshold limit value (TLV) of 0.3ppm, which is based on irritation in less sensitive workers but not protecting the most sensitive workers.[94] Peak values classification in comparison to the ACGIH standard of 0.3ppm for Threshold limit value showed that only one job can be classified to be below the limit and the rest of the jobs as above the ACGIH limit. Red colour shows peak values above ceiling limit and yellow colour shows peak values below ceiling limit (See table 3.10).

Unique identity number is used to identify the areas on the schematic sketches attached (see appendix 1). The mean 8-hour concentration shows that all areas had formaldehyde levels higher than the most typical indoor areas.[96] The comparison of the area measurements peak values on the day of measurement to the ACGIH threshold limit value of 0.3ppm shows only two storage areas below the limit. The areas below the limit are the waste storage area and general storage area next to the preparation room (Area 5 and 9 - see appendix 1). However, none of the 8-hour TWA mean-exposure was higher than the OSHA PEL-TWA of 0.75ppm (table 3.7 in page 48).

Table 3.10: Comparison between ACGIH Threshold Limit and peak values

Task	Peak Day 1	Peak Day 2	Peak Day 3	Peak-Mean (std dev)	Peak Min	Peak Max
Receiving cardio-respiratory organs	0.32	0.59	1.64	0.85 (0.70)	0.32	1.64
Looking for photography cases	5.65	5.21	6.73	5.86 (0.78)	5.21	6.73
Cleaning	0.49	0.39	0.41	0.43 (0.05)	0.39	0.49
Removing Formalin from Lungs	1.28	5.76	5.24	4.09 (2.45)	1.28	5.76
Removing water from Lungs	2.46	0.90	-	1. 68(1.10)	0.90	2.46
Transferring lungs from round to red lid buckets	6.86	2.62	0.69	3.39 (3.16)	0.69	6.86
Lung Examination	0.95	2.73	2.64	2.11 (1.00)	0.95	2.73
Recording of diagnosis	0.75	1.16	0.65	0.85 (0.27)	0.65	1.16
Refilling formalin plastic bags after lung examination	1.38	1.63	1.30	1.44 (0.17)	1.30	1.63
Assisting pathologist with weighing, cutting and removal of organs	1.90	1.01	2.37	1.76 (0.69)	1.01	2.37
Cleaning tools	0.86	1.37	1.09	1.10 (0.26)	0.86	1.37
Taking photographs	2.57	3.77	1.58	2.64 (1.10)	1.58	3.77
Organs removal to storage	0.56	1.03	0.60	0.73 (0.26)	0.56	1.03
Discarding	5.07	3.72	4.36	4.38 (1.59)	3.72	5.07
Manual Formalin preparation	5.43	-	7.68	6.56 (2.29)	5.43	10
Waste box removal	0.42	0.48	0.44	0.44 (0.31)	0.42	0.48
Dispatch	0.79	1.53	0.49	0.93 (0.54)	0.49	1.53
Refilling formalin plastic bags ï clients	0.75	1.00	1.11	0.95 (0.18)	0.75	1.11
Transfer ï Tech	1.34	1.87	-	1.6 (0.37)	1.34	10
Transfer ï Assistant 1	9.38	5.07	2.77	5.74 (3.36)	2.77	9.38
Transfer ï assistant 2	1.35	2.33	3.72	2.47 (1.19)	1.35	3.72
Checking tools before examination	1.74	1.05	1.16	1.32 (0.37)	1.05	1.74
Laoding Citadel	0.37	0.60	0.51	0.49 (0.12)	0.37	0.60
Inflating lung(s)	2.66	3.96	3.31	3.31 (0.65)	2.66	3.96
Washing Buckets	0.78	1.25	2.62	1.55 (0.96)	0.78	2.62
Labeling	1.13	0.87	0.51	0.84 (0.31)	0.51	1.13
Filing organs	0.61	0.3	2.87	1.26 (1.40)	0.30	2.87
Looking for Special cases	0.30	027	0.21	0.26 (0.05)	0.21	0.30

Table 3.11: The area 8-hour concentration and peak readings for each area measured

Unique Identity Number	Area	8-hour Concentration Day-1	8-hour Concentration Day-2	8-hour Concentration Day-3	Mean 8-hour Concentration (std dev)	Peak Day-1	Peak Day-1	Peak Day-1	Mean Peak (std dev)
1	Transfer Room	0.30	0.31	0.45	0.35 (0.08)	1.10	1.13	0.92	1.05 (0.11)
2	Lung room	0.24	0.41	0.30	0.32 (0.09)	0.52	0.53	0.57	0.54 (0.26)
3	Main and small storage areas	0.44	0.47	0.33	0.41 (0.73)	0.62	0.60	0.43	0.55 (0.10)
4	Formalin Water room	0.17	0.16	0.09	0.14 (0.04)	0.60	0.28	0.19	0.36 (0.22)
5	**Waste storage**	0.03	0.01	0.01	0.02 (0.01)	0.07	0.03	0.12	0.07 (0.05)
6	Formaldehyde(Formalin)preparation laboratory	1.87	1.08	0.6	1.18 (0.64)	6.31	2.47	0.97	3.25 (2.75)
7	Next to Laboratory mangers office	0.12	0.12	0.15	0.13 (0.02)	0.21	0.23	0.33	0.26 (0.1)
8	Next to Administrative Clerks office	0.22	0.18	0.22	0.21 (0.02)	0.51	1.03	0.18	0.57 (0.42)
9	**General storage area-Next to formalin preparation room**	0.5	-	0.01	0.03 (0.28)	0.10	0.10	0.03	0.08 (0.40)

3.5 Physical measurements

Areas like cardio respiratory organs storage area, formaldehyde preparation room and waste box area where extraction was done had low levels of extraction air speed to lower the levels of formaldehyde significantly from fugitive formaldehyde fume emissions. The fugitive formaldehyde fumes are from containers found in these areas. The areas indicated in table 3.13 are shown in schematic diagram of appendix 1.

Table 3.13: Ventilation speed and volumetric flow study results compared to recommended specifications.

Area	Diffuser / slot velocity	Measured Air speed (m/s)	Recommended air speed	Volume size in m^3	Flow quantity M3/s	Air changes per hour	Best Practice – Air changes per hour.
Transfer room	B1-Supply	0.21	-	86.34	0.140	5.8	15
	B2-Supply	0.25	-	86.34	0.185	7.7	15
	B3	0.12	3.5	-	-	-	-
	B4	0.03	3.5	-	-	-	-
	B5	0.01	3.5	-	-	-	-
	B6	1.95	3.5	-	-	-	-
	B7	1.84	3.5	-	-	-	-
Lung Function Room	C1	0.15	-	-	-	-	-
	C2	0.13	-	-	-	-	-
	C3	0.05	3.5	-	-	-	-
	C4	0.08	3.5	-	-	-	-
	C5	0.07	3.5	-	-	-	-
	C6	0.17	-	-	-	-	-
	C7	0.39	-	-	-	-	-
Main stage Area	D1	0.76	-	-	-	-	-
	D2	0.57	-	-	-	-	-
	D3	0.58	-	-	-	-	-
	D4	0.87	-	-	-	-	-
	D5	0.62	-	-	-	-	-
	D6	0.71	-	-	-	-	-
Small storage area	D7	0.43	-	-	-	-	-
	D8	0.30	-	-	-	-	-
Waste box area	G	0.60	-	-	-	-	-
Formaldehyde water preparation room	H1-CEILING	0.47	-	78.36	0.140	6.4	15
	H2	0.24	-	-	-	-	-
	E1	0.21	-	-	-	-	-
	E2	0.30	-	-	-	-	-
Formaldehyde preparation room	E	1.36	-	-	-	-	-

CHAPTER 4

Discussions

This chapter discusses the exposure to formaldehyde of pathology laboratory employees in terms of the task description and observations, formaldehyde exposure levels and physical measurements taken. Results are discussed in relation to the study design structure.

Observational study

The observations revealed that 11 of the 28 tasks were being performed according to written SOP. Eight of the 28 tasks were done with some deviation from the written SOP. The remaining nine tasks did not have SOP.

Those that were done according to SOP are transfer of cardio-respiratory organs, opening and transferring organs into fresh formalin white buckets, inflating the cardio-respiratory organs, removing formalin and replacing with water (rinsing of organs), refilling of the plastic bags with formalin after examination, labeling, and the discarding of cardio-respiratory organs. The tasks with some deviation from the SOP included; Receipt of the cardio-respiratory organs, preparation of cardio respiratory organs before examination, checking tools and PPE for pathologist before examination, examination of cardio respiratory organs - involved with weighing, cutting, sorting and packing and unpacking of the organs, removal to storage of cardio-respiratory organs and discarding. Those tasks without SOP were cleaning of the tools and floor after cardio-respiratory organ examination, filing, loading citadel machine, transfer of waste boxes to main storage room, manual preparation of formaldehyde, looking for photography bucket cases, looking for special cases inside the buckets; packing and sorting for on the shelf (special cases), washing of white round buckets and cleaning the storage shelves in the lung and storage rooms.

Although a sizeable (9/28) number of tasks are done without SOPs, they are mainly irregular and involve mainly handling containers without opening them and generally last for a short duration. Hence, are generally of lower exposure than those tasks done as per written SOP or those with slight deviations to written SOP’s. However, SOP can still be of value for such tasks.

Physical measurements

The ventilation factors influencing the personal exposure were the placing of extraction diffusers far from sources of exposure and the low formaldehyde extraction rates of the installed local extraction ventilation system. This is as a result of poor designs and inferior materials used to construct the pipes and basins. The pipes were found to leak and spilled on to the floor with very high potential of exposure for the people involved in cleaning these spills.

The British standard air speed (velocity) for embalming areas is 3.5 meters per seconds (m/s).[95] This is for the slotted table where embalming is done. On the other hand, the National Funeral Directors Association (NFDA) of USA recommends at least 15 air exchanges per hour for the preparation room where embalming is performed and high level of exposure to formaldehyde is expected.[96]

The supply of air to formaldehyde water preparation is by E diffuser and supply of air to transfer room is by B1 and B2 diffuser. The total air supplied to water preparation room is 6.4 and to transfer room is 13.5(7.7+6.8) air changes per hour respectively. For both cases the results are lower than recommended 15 air changes by National Funeral Directors Association (NFDA) of USA. This is also true for the punch holed tables in the transfer room and lung function room where the air speed measured was below 3.5 m/s and close to zero. The recommended standard for the embalming tables is 3.5m/s.

Personal Measurements

Measurements were taken for various activities and STEL and TWA readings were calculated. These measurements are used to assess the level of exposure for the workers in different groups. The method used for the measurements of exposure was a shadow sampling. The shadow sampling has not been used in South Africa (SA) before; it was used to measure the exposure of petroleum truck drivers were useful information about their exposure was obtained.[97]

In this study, there was good results obtained which confirmed high exposure to employees in different groups. These groups were classified as assistants, technologists and the pathologist. The results tabulated in tables 3.7, 3.8, 3.9 and 3.9 confirm over-exposure for employees in these different groups when analyzing and comparing results with STEL and TWA for ACGIH threshold value of 0.3ppm. Many studies indicated that the exposure to formaldehyde could result in genotoxic effect in pathology laboratory workers. [98-100]

In general, exposure to formaldehyde was highest for short term exposure levels and long term exposure for (STEL and peak values) assistants. Pathologist long term exposure levels were higher than those of technologists.

Daily exposure levels for assistants were highest of the three exposed groups; the technologists followed this group or job category with the pathologist having the lowest levels. The highest exposure group was the assistants who are responsible for most tasks involving high exposure level and the least exposed are the pathologist. This is to be expected as per the high exposure tasks for the assistants group and mostly medium exposure group for the technologist and low task exposure job for pathologist with at least one high exposure task of lung examination. Further variance analysis of the log transformed data showed that the within job variance was higher than the between job variance. This observation was supported by the significant daily exposure variation observed for assistants and technologists. The daily exposure levels for pathologists did not vary daily. This is to be expected as the daily duties of the assistants and technologist was more varied than that of the pathologists and involves a lot of various tasks of low, medium and high exposure in any given day. The only exposure source for the pathologist is lung examination task while the rest of the day is mostly spent in an office environment with low exposure levels.

In line with the daily exposure results, the TWA values were also highest for assistants and lowest for pathologists. This confirms that assistants have the highest cumulative exposure overtime while pathologists have the lowest. Therefore assistants will be at a higher risk of the chronic health effects of long-term formaldehyde exposures. This is true as all the values were proven to be higher than MRL, NOEAL and the REL values.

The STEL and peak values for all three jobs reveal that assistants have the highest mean values while the technologist have the lowest mean values. This is in agreement with the high exposure classification of most assistantsôtasks as compared to the medium and low exposure classification of technologist tasks and the high and lows exposure tasks for pathologists. The fact that pathologist were having higher STEL and peak values than technologists reflect the high short term exposure associated with slung examination task.

This is related directly to the pathologist observed close position to cardio-respiratory organs when doing examination and organs dissection. These results show that although pathologists have lower cumulative exposure (daily and 8-hour TWA) than technologists, they can have higher short term exposure than technologists. Hence, assistants and pathologists experienced irritation of the eyes and respiratory tract the most.

Comparing the STEL to South African OEL STEL and OSHA STEL showed that assistants and pathologists were above the limit but technologists were not. However, compared to the NIOSH STEL, all job-types were above the limit. It should be noted however that the NIOSH STEL of 0.016 is below the detection limit of the 0.05ppm of the formaldehyde measuring instrument. Comparing the observed peak values in the study to ACGIH ceiling limits of 0.3ppm confirm over-exposure for employees in all groups. The reason for using ACGIH is because the SA does not have a ceiling limit value for formaldehyde. The ceiling limit is the instantaneous value, which should not be exceeded at anytime. However, in a case where one does not have ceiling limit value, peak values could be used and have same meaning as the ceiling limit.

It is of importance to maintain exposure levels below 0.3ppm as acute exposure to formaldehyde is known to have negative health effects ranging from irritation of the eyes and respiratory tract to headache, throat burning sensation and sensitization of the skin.[3] The acute effects of formaldehyde on human at levels above 5ppm is an intolerable irritation of the eyes and respiratory tract, and at 10ppm and above, a choking sensation occurs.[2] According to Fasset and Patty, concentration levels above 50ppm, even at short duration, can cause serious injuries to the eyes and the respiratory organs.[29] However, in this study, the formaldehyde measuring instrument could not detect values above 10ppm. However, certain measurements above 10ppm were recorded but were not included in this report. This suggests that exposures above 10ppm could have been experienced but were not quantified because our sensor could not reliably measure anything above 10ppm.

It has also been reported that cancer health effects of formaldehyde exposure is related with peaks of high concentrations than with long time exposure at low levels.[98] the combined effects of high exposure levels and high peak exposures can be more potent than the high peak exposures alone. This implies that the risk of cancer health effect is higher among the assistants and lowest among the technologist. The pathologists are the second highest group due to high peak exposures during lung examination.

Area measurements

For all the areas were measurements were done, only two areas had peak levels below the 0.3ppm ceiling limit. The transfer room and the area next to the clerk’s offices, close to transfer room, gave the highest readings for peak values. This is as the result of most high exposure tasks such as transfer of organs; inflating the organs or refilling plastic bags tasks being performed in this room and the tendency by laboratory employees to leave the main transfer room door open for long period allowing the leakage of formaldehyde to the surrounding areas such as the area next to the clerk’s office or corridor.

CHAPTER 5

Conclusions and Recommendations

Personal behavior, job type and the general designs of the laboratory played important part in influencing the exposure to formaldehyde. The assistantsôjob involved more contact with the formaldehyde than that of technologist and pathologist. Technologistsô job exposure profile tends to be generally of low and medium exposure. The pathologist spent the least time in contact with the formaldehyde.

The results showed exposures among the employees of all categories in this study, with laboratory assistants being the most exposed.

It has been found that when following the hierarchy of control for stressors in the industry, the engineering method, plays an important role where the elimination and substitution is not possible. The results concluded that ventilation, as an engineering method is best suited to control exposure to formaldehyde gas/fumes. This has been demonstrated in many other studies to be good in reducing the exposure to formaldehyde to be below control limit in Japan. [97]

The two important factors influencing the personal exposure were the placing of extraction diffusers far from sources of exposure for all high exposures tasks, the job type and the individual work habits of leaning towards the formaldehyde impregnated organs. Actions such as delaying the cleaning of spillages and allowing it to remain on the floor or surface for long period increase the evaporative rate and a chance of exposing employees to high levels of formaldehyde gas/ fumes.

Traditional methods used in occupational hygiene hierarchy of stressor control are:
Elimination, Substitution, Engineering, Administrative and Personal Protective Equipment

This hierarchy of control method is the most effective in controlling occupational exposures to formaldehyde as it is with any occupational hygiene stressor. The hierarchy of control recommendation for the formaldehyde in the report also follows this method.

Discarding occurs rarely or at least once in every six months. This process is a very hazardous task and requires careful control of high level of formaldehyde fumes released. Current process is done in unventilated area with low air velocity. The most ideal situation is to have a well-ventilated area with dedicated extraction system for removal of formaldehyde fumes. Alternatively, a portable local extraction system can be used with disposing drums in a ventilated area. The result of residential homes study in Québec City, Canada, indicates that ventilation effectively decreases formaldehyde concentrations.[102] This was also the case in a Japanese study conducted for anatomy dissection classes. [103]

Revision and improvement in the performance of the ventilation system is needed. This is especially needed for tasks that are carried out in formaldehyde preparation room, transfer room and lung examination room. These areas involve tasks that produce more formaldehyde gas and needs good ventilation designs to lower the exposure level to acceptable levels comparable to international standard set by ACGIH. The current ventilation installed has air velocity/speed below the required minimum of 3.5 m/s(meters per second) in all the areas mentioned.[95]

The current newly installed local extraction system is ineffective. The NIOH needs to request the responsible contractor to supply them with the design specification and the commissioning data for proper hand-over of this installed ventilation system. The data should clearly demonstrate the match between design and the performance based on sound and best formaldehyde control with LEV system. There should be clear information on what is the basis of their design specification. The specification should demonstrate ability to lower the formaldehyde levels to well below the standard for South Africa and comply with international best practice design specifications.

The hazardous chemical substances legislation requires that employees that are exposed to hazardous chemical substances should undergo Medical surveillance as per medical doctor recommendation.[83]The employees working in the laboratory are exposed to formaldehyde and need to be examined by the medical doctor at least bi-annually.

Training on handling formaldehyde and removal of spill by employees is very important. Regular retraining and awareness should be given to employees and appropriate spill kits made available especially during transfer and discarding task as these processes produced high spillages. The training should involve every person involved in the use, storage or transport of formaldehyde and instructions on the associated dangers and necessary precautions for self-protection. The use of goggles, gloves, apron, respirator and protective clothing at all times when handling formaldehyde should be encouraged, monitored and enforced.

Formaldehyde, and other carcinogenic substances, should ideally be kept to a minimum by methods other than the PPE, such as engineering controls. Where such controls are not effective, the correct formaldehyde respirator with a TB filter fitted should be used. The current N95 respirators in use are not the most appropriate for the protection against formaldehyde fumes. There are special formaldehyde respirators that can be used. These respirators can also allow the TB bacteria filter to be inserted in the cartridge for the protection of employees to active TB bacteria that survives after preservation by formaldehyde. This may be the main reason why current N95 respirators are used. The N95 are very good in protection against active TB bacteria.

People from the same or different ethnic grouping come in different facial shape, facial size and facial dimension. This also applies to the different manufacturers of respirators who also do not produce respirators of similar shape and/or size. As result, the gloves from different manufactures rated as small, medium or large are not necessarily of equal size.
The only way to ensure proper fit is to test if specific chosen respirator forms a correct seal around the individual person, respirator fit testing needs to be performed annually and records kept for each employee. Replacement of respirator fit tested should only be done and old respirator disposed off when a new respirator fit test has been done. This is also true for people working with formaldehyde. They require the fit testing to be done on the respirator chosen for pathology laboratory use. The testing should be repeated at least every two years as a person getting fat or thin may affect its fit.

Other control measures for dermal exposure using clothes and laboratory coats with aprons should also not be neglected. Assistants should change gloves regularly to avoid the break-through of formaldehyde. The glove change should be matched to the determined glove breakthrough factor.

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APPENDIX 1

SCHEMATIC DIAGRAMS OF THE

PATHOLOGY LABORATORIES

AND STORAGE AREAS

APPENDIX 1.1: Transfer Room

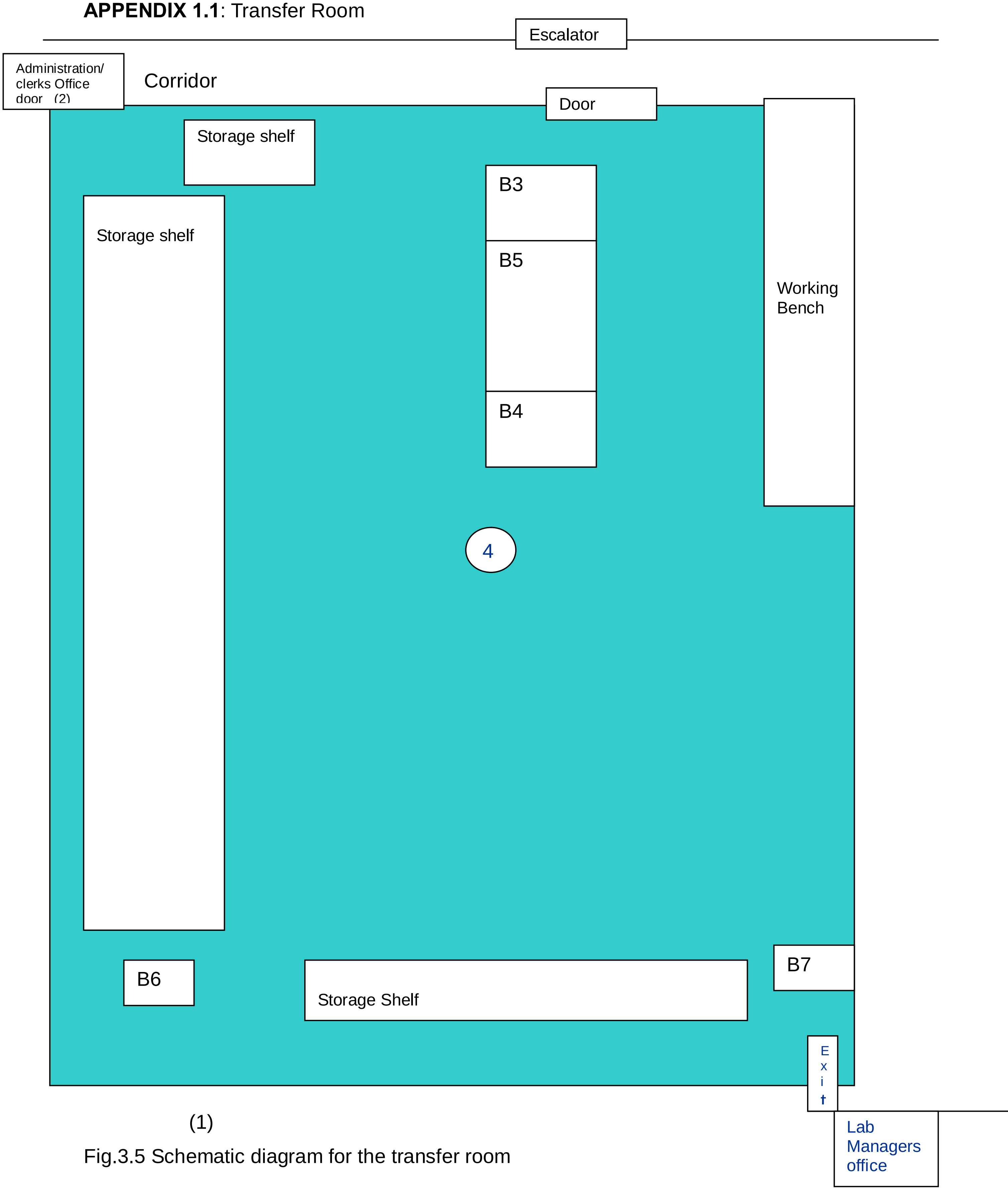

Fig.3.5 Schematic diagram for the transfer room

APPENDIX 1.2: Lung Room

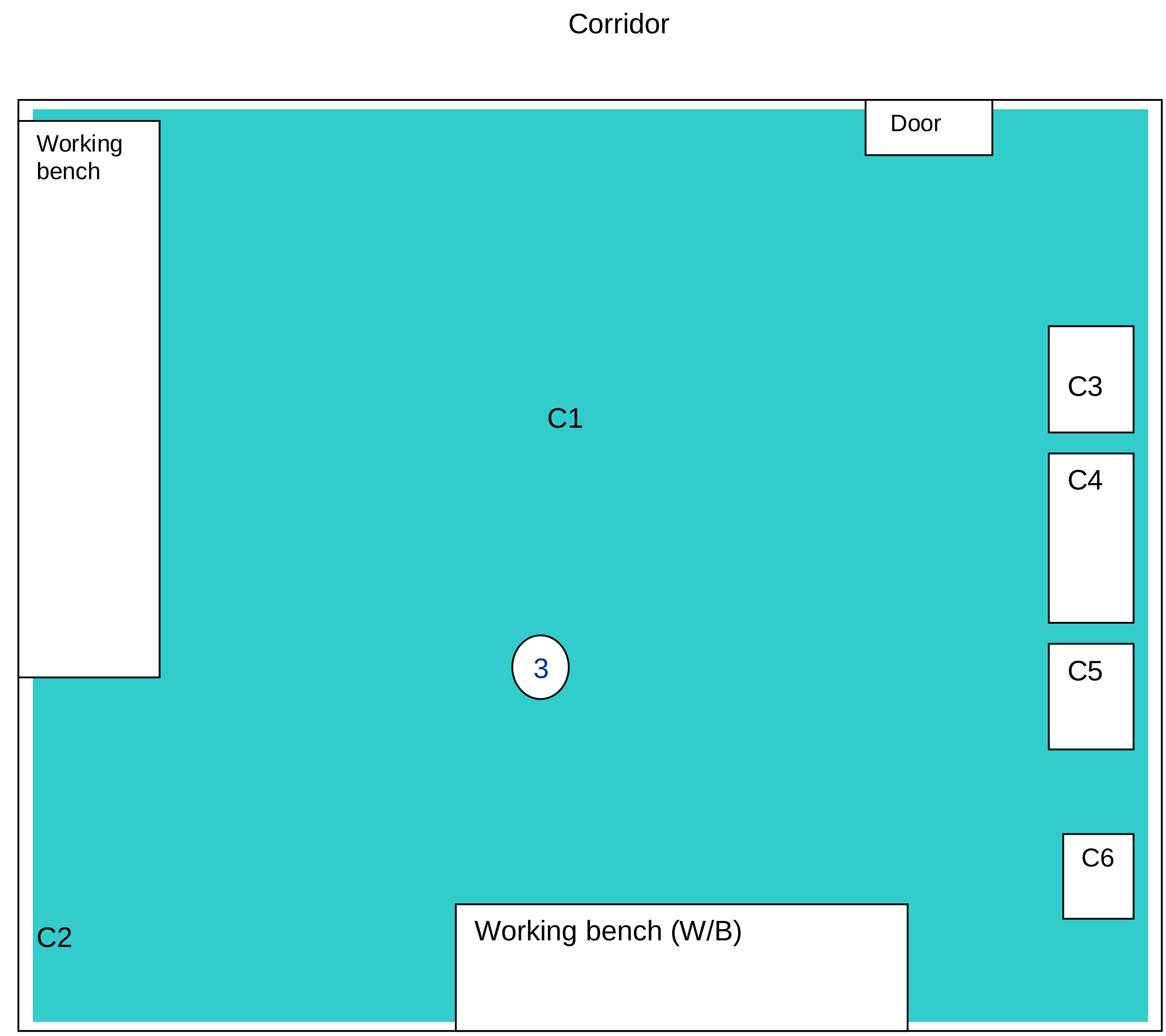

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Fig. 3.6 Schematic diagram for the lung room

APPENDIX1.3: Main Storage Area

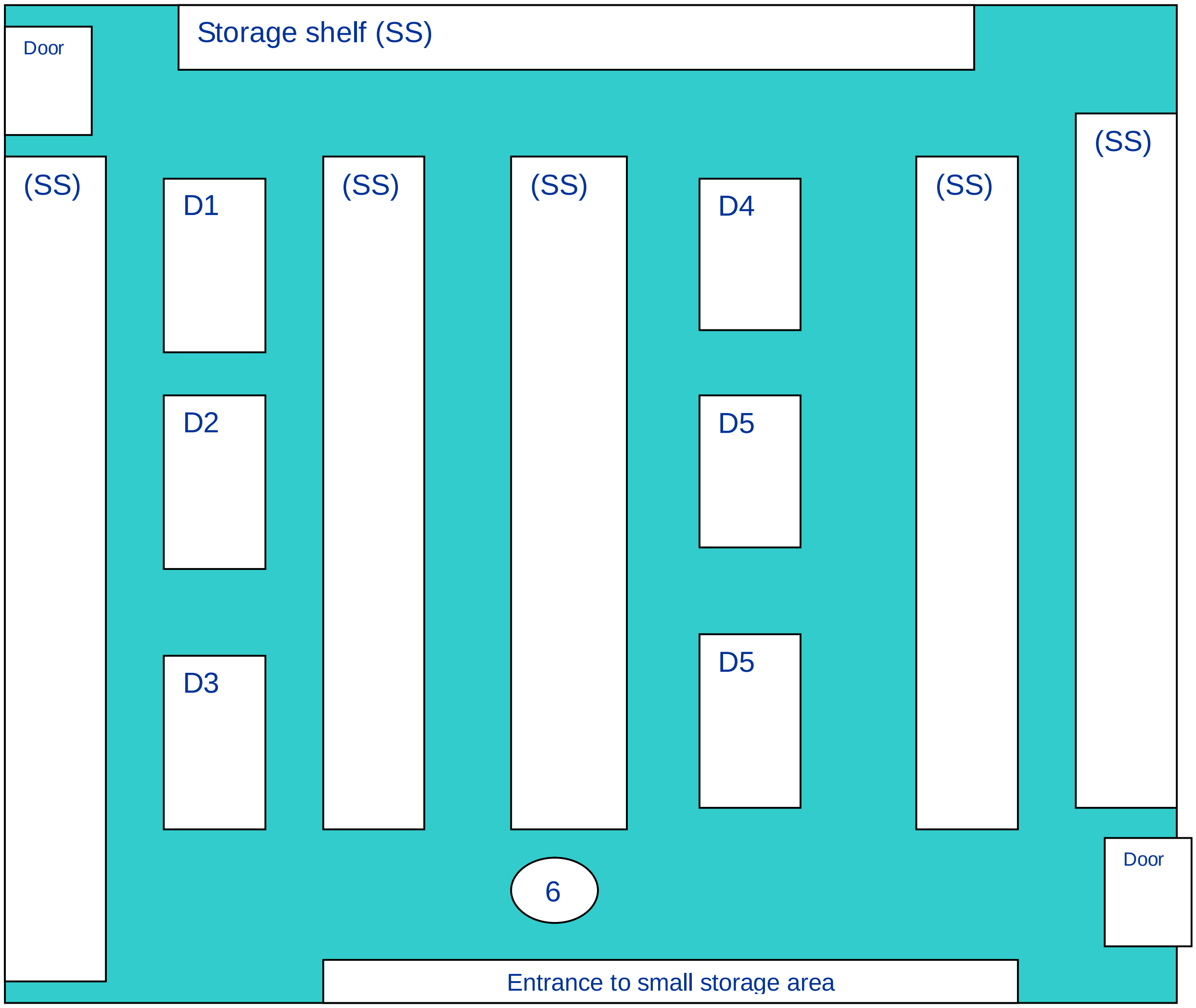


Fig.3.7 Schematic diagram for the main storage area

APPENDIX 1.4: Small Storage Area

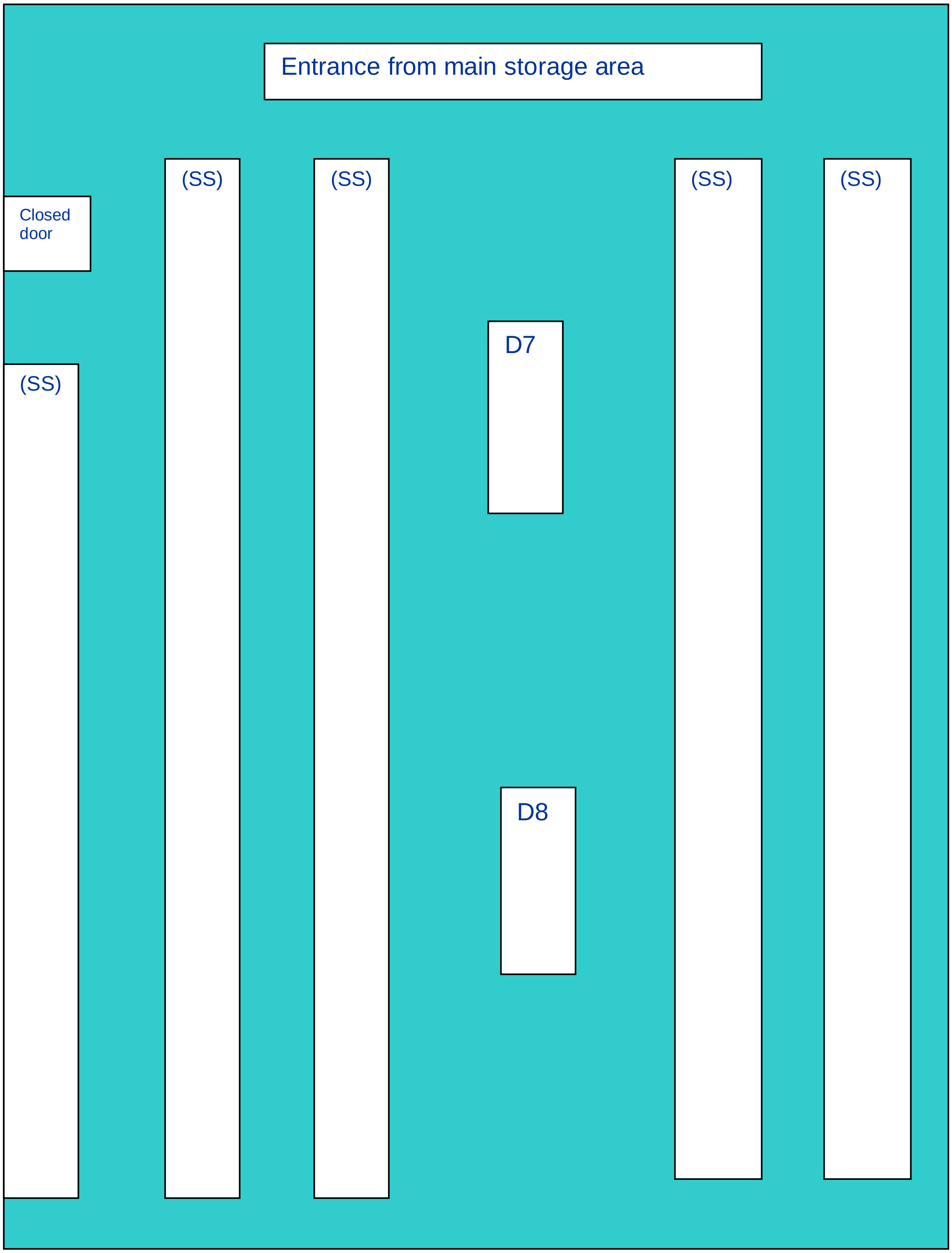


Fig 3.8 Schematic diagram for the small storage area

APPENDIX 1.5: Formaldehyde Water Preparation Room

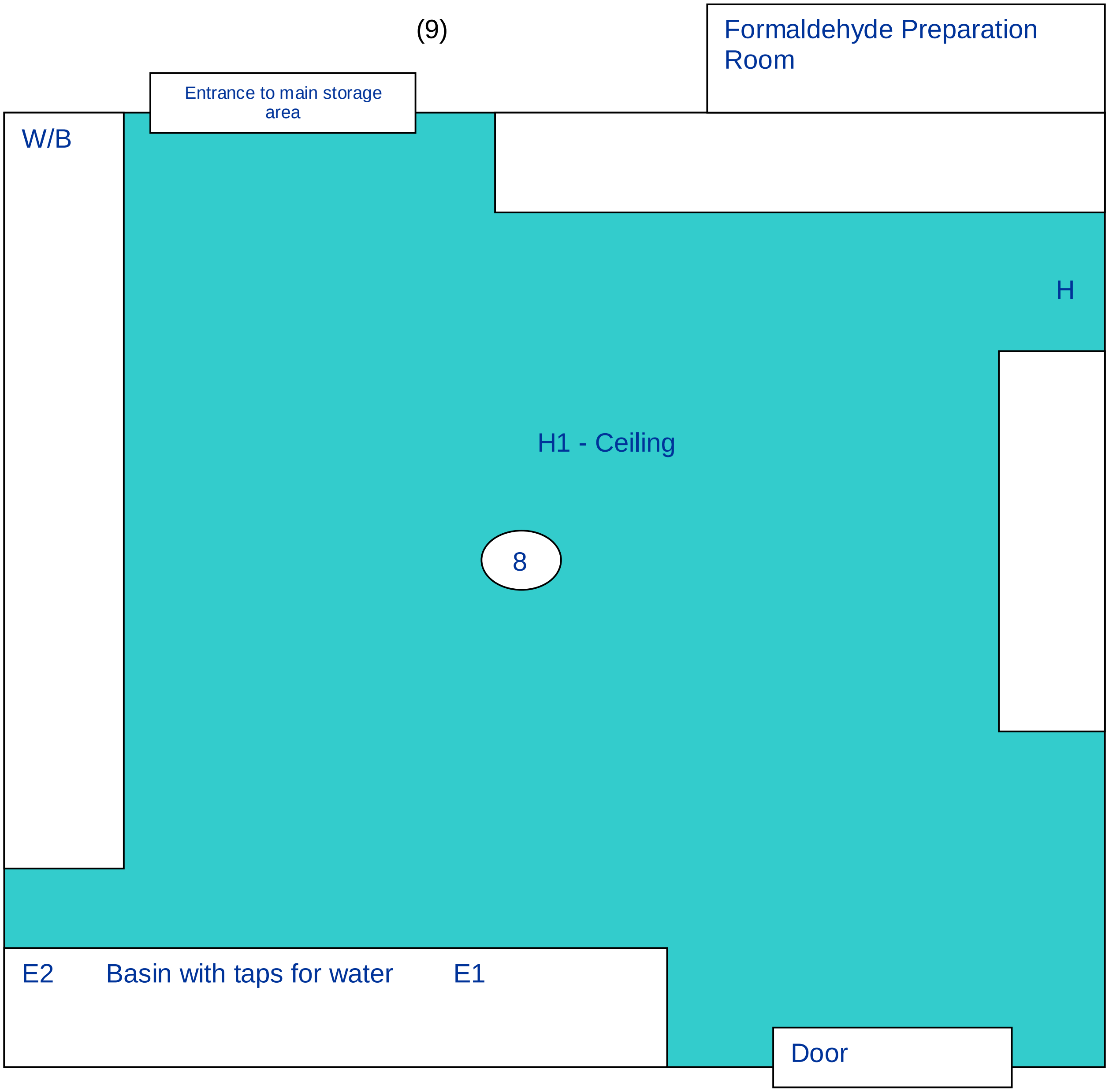


Fig 3.9 Schematic diagram for formaldehyde water preparation room

APPENDIX 1.6: Waste Storage Room

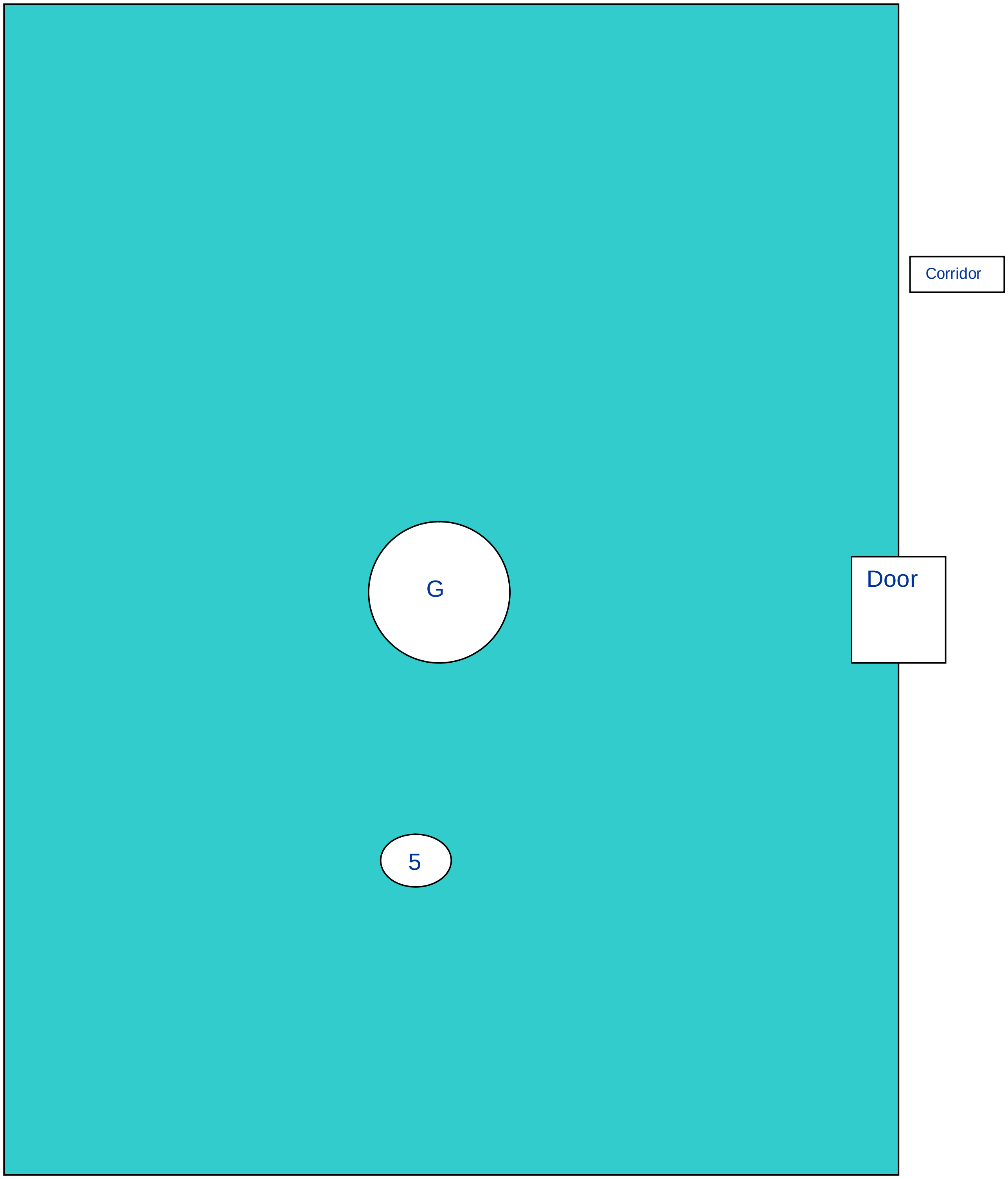


Fig 3.9 Schematic diagram for the waste storage room

APPENDIX 1.7: Formaldehyde Preparation Room

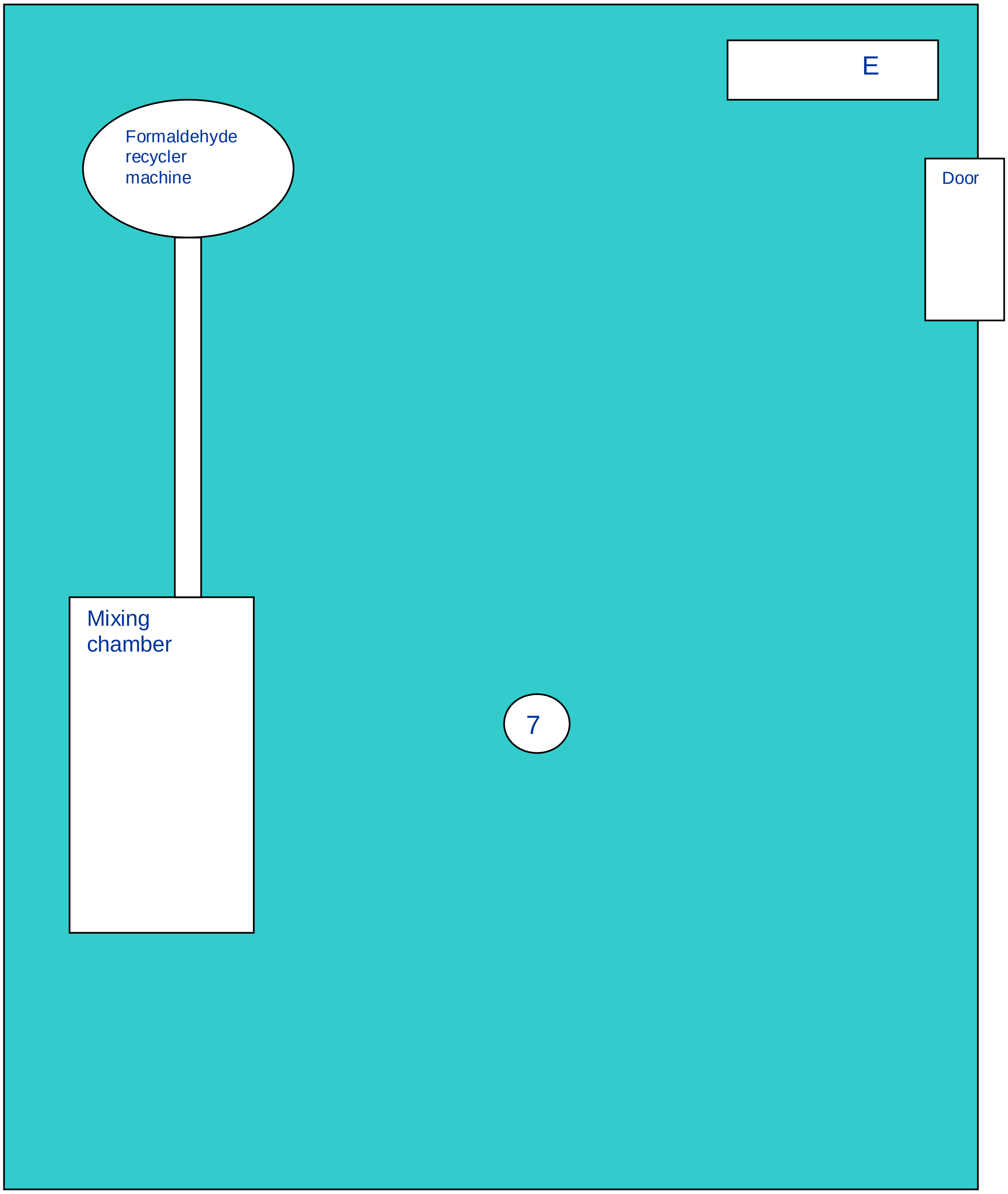


Fig. 3.10 Schematic diagram for the formaldehyde preparation room

APPENDIX 2

ETHICS CLEARANCE CERTIFICATE

APPENDIX 2: Clearance Certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Ntsuba

CLEARANCE CERTIFICATE | **PROTOCOL NUMBER M070430**

PROJECT	Characterization of Airborne Concentrations of Formaldehyde in a pathology unit
INVESTIGATORS	Mr HS Ntsuba
DEPARTMENT	Occupational Hygiene
DATE CONSIDERED	07.05.04
DECISION OF THE COMMITTEE*	APPROVED UNCONDITIONALLY

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 07.06.14 **CHAIRPERSON** ....
(Professors PE Cleaton-Jones, A Dhai, M Vorster, C Feldman, A Woodiwiss)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Baimoh B

DECLARATION OF INVESTIGATOR(S)

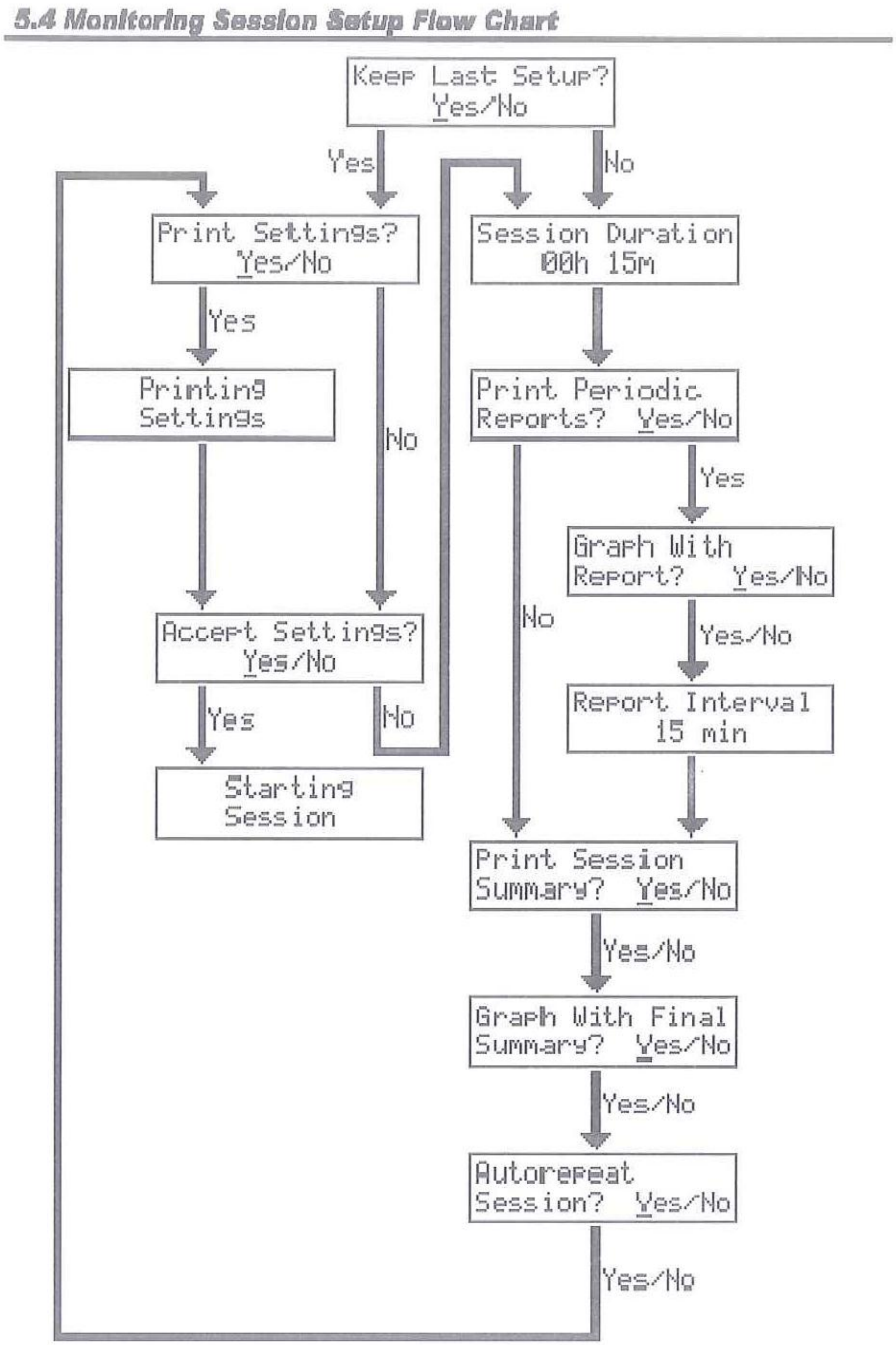
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress report.

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 3

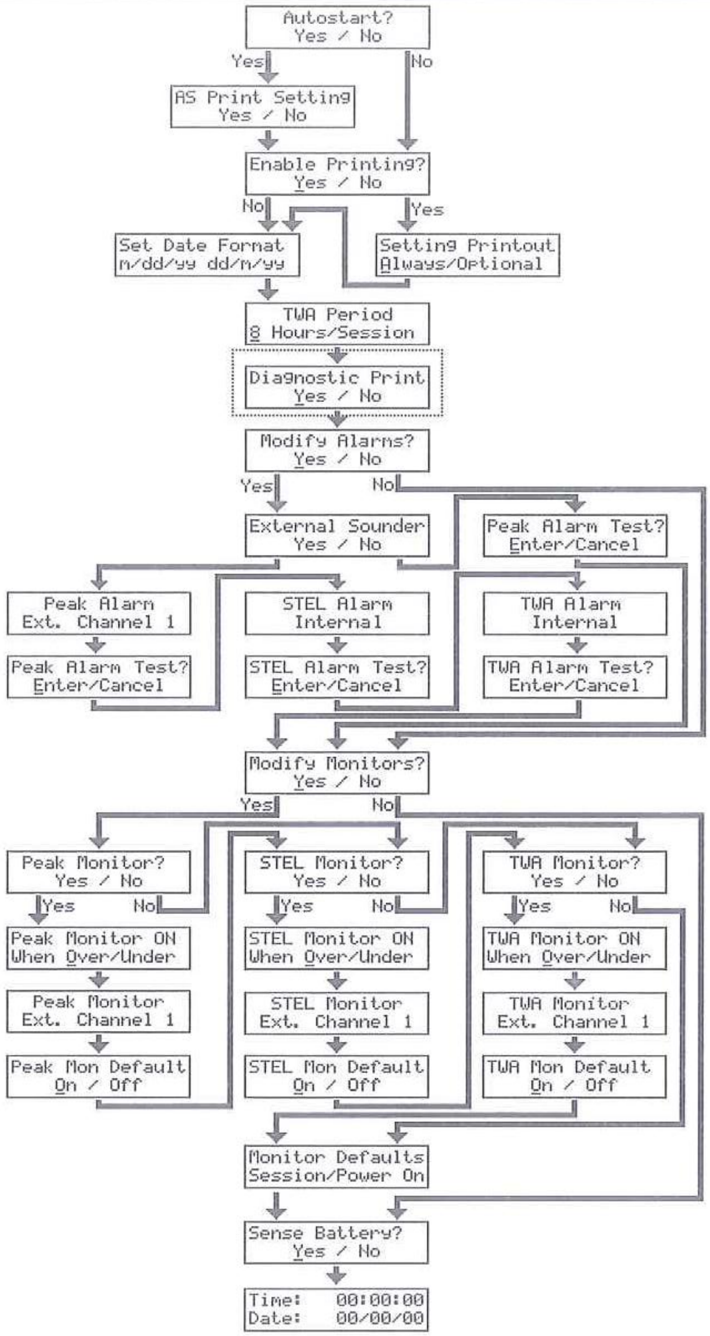
MONITORING SESSION AND SYSTEM SETUP FLOW CHART

APPENDIX 3.1: MONITORING SESSION SETUP FLOW CHART



APPENDIX 3.2 SYSTEM SETUP FLOW CHART

5.5 System Setup Flow Chart



APPENDIX 4

CONSENT FORM

APPENDIX 4: Consent Form

NATIONAL INSTITUTE *for* OCCUPATIONAL HEALTH

NIOH

106 Joubert Street Ext ŏ PO Box 4788 Johannesburg 2000 South Africa ŏ Tel: 27 11 712 435 ŏ Fax: 27 11 720 6535 Enquiries: H Ntsuba E-mail Address: Hlosi.ntsuba@nioh.nhls.ac.za Web: ww.nioh.ac.za

Information Sheet – Project Number 926501/Protocol M070430

Good day, my name is Hlosi Ntsuba from the occupational Hygiene unit of the National Institute for Occupational Health (NIOH).

We are conducting a study to assess the exposure levels of formaldehyde in the pathology unit of this institute, the NIOH. We will be doing this by means of a formaldehyde meter, note taking, photographs, and videos. Photographs and videos will be destroyed once the project is completed and no faces of individuals will be shown on the research report.
We will follow you and place the formaldehyde meter in your breathing area (about 30cm around your face) while you are performing your tasks for the duration of different tasks identified that you perform in a day. All the formaldehyde measurement and information obtained will be used for the purpose of research only. The measured results will be analysed to determine the exposure levels of formaldehyde and thus the effectiveness of your engineering controls in place.

The report will be sent to your management regarding the generic recommendations to reduce exposure levels in your workplace.
The results will be used to fulfil, in part, the requirements for Hlosi Ntsuba Masters in Public Health (Occupational Hygiene) at Wits University and to publish a scientific paper on our findings. The results will be published anonymously without your name and the paper will be sent to your management for pre-approval before it is published.
This study will help us to have a better idea of any risks to health for workers in different job categories employed by the Pathology Unit.

You have the right to refuse to participate in this study and this will not count against you in any way. You can also change your mind at any time during the study. We will carry out the study during normal working hours from Monday to Friday and be of as little inconvenience to you as possible.

Any personal information will be kept confidential and all information will be analysed and published anonymously i.e. only study numbers (and not your name) will be entered into the database. Please feel free to contact me (Mr. Hlosi Ntsuba ï 011 7126435) at any time for any information.

Please sign the consent form below if you agree to participate in the study.
Thanking you in advance

Please sign the consent form below if you agree to participate in the study-.
---cut here with a ruler-------

"I agree to be part of the study- Airborne concentration of formaldehyde in a pathology unit - Project Number 92650/ Protocol M070430**".**

Name:é é é é é é é é é é é é é é é é é é Signature:é é é é é é é é é é é é é é

I also agree to be photographed and video taped during the research study- Airborne concentration of formaldehyde in a pathology unit - Project Number 926501/ Protocol M070430".

Name:…………………………………………..Signature:……………………………………Date………………